USE OF IMAGING SERVICES: PROVIDING APPROPRIATE CARE FOR MEDICARE BENEFICIARIES

HEARING

BEFORE THE

SUBCOMMITTEE ON HEALTH

OF THE

COMMITTEE ON ENERGY AND COMMERCE
HOUSE OF REPRESENTATIVES

ONE HUNDRED NINTH CONGRESS

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USE OF IMAGING SERVICES: PROVIDING APPROPRIATE CARE FOR MEDICARE BENEFICIARIES

TUESDAY, JULY 18, 2006

HOUSE OF REPRESENTATIVES,
COMMITTEE ON ENERGY AND COMMERCE,
SUBCOMMITTEE ON HEALTH,
Washington, DC.

The subcommittee met, pursuant to notice, at 10:13 a.m., in Room 2123 of the Rayburn House Office Building, Hon. Nathan Deal (Chairman) presiding.

Members present: Representatives Upton, Gillmor, Norwood, Cubin, Shimkus, Pickering, Pitts, Ferguson, Rogers, Myrick, Burgess, Towns, Pallone, Eshoo, Green, Capps, Dingell (ex officio), and Deal.

Staff present: Melissa Bartlett, Counsel; Ryan Long, Counsel; Brandon Clark, Policy Coordinator; Chad Grant, Legislative Clerk; Bridgett Taylor, Minority Professional Staff Member; Amy Hall, Minority Professional Staff Member; and Jessica McNiece, Minority Research Assistant.

MR. DEAL. We will call the meeting to order and I will recognize myself for an opening statement for this hearing.

First of all, I am proud to say that we have two very good expert panels of witnesses again today. They are going to help us examine the concerns that have been raised by MedPAC, CMS, and others regarding the rapid growth of the use of imaging services in Medicare. Today's hearing will also provide a forum for witnesses to provide suggestions for how to determine what is proper versus improper growth of services and how to best control over-utilization or misuse of services.

Over the past few years, there has been rapid growth in the volume of imaging services paid under Medicare fee-for-service. MedPAC has found that Medicare spending for imaging services paid under the physician fee schedule nearly doubled between 1999 and 2004, from $5.4 billion per year to $10.9 billion per year. In addition, the volume of imaging services has grown at almost twice the rate of other physician services. Clearly, this level of growth is unsustainable. Some growth in use of imaging services is argued to be attributable to technological innovations that allow physicians to better diagnose disease. However, many observers argue that such growth may reflect overuse or misuse of

imaging services. MedPAC has determined that spending for MRI, CT, and nuclear medicine has grown faster than other imaging services. Accordingly, MedPAC has identified some factors that may contribute to the rapid growth in volume and intensity in imaging services, including one, the possible misalignment of fee schedule payment rates and costs, two, physician's interest in supplementing their professional fees with revenues from ancillary services, and three, patients' desire to receive diagnostic tests in more convenient settings.

In its March 2005 report to Congress, MedPAC recommended that Congress direct the Secretary to set standards for physicians interpreting or performing diagnostic imaging services. This is a recommendation I hope my colleagues on this subcommittee will carefully consider as we start to look at possible solutions to this problem.

As my colleagues are no doubt aware, the Deficit Reduction Act of 2005 included a provision that caps reimbursement for the technical component of imaging services performed in a physician's office at the hospital outpatient payment rate. Imaging services paid under the physician fee schedule involve two parts, a technical component and a professional component. The technical component of the payment covers the cost of the equipment, supplies, and non-physician staff. The DRA provision capping the technical component of physician payment for imaging services was intended to move toward payment neutrality across sites of service delivery. This provision takes effect January the 1st of 2007 and will save the Medicare program almost $3 billion over 5 years. Of course, many physician groups and industry stakeholders are pushing for a delay in the effective date of this provision. However, it is important to remember that these savings were a major financial component in preventing physicians from taking the 4.4 percent reduction in fee schedule payments that was scheduled to be implemented under the SGR formula for 2006.

Unfortunately, few groups are offering legitimate offsets in order to pay for this requested delay in implementation. It reminds me of the lyrics I believe from an old Bobby Gentry song that says "Everybody wants to go to heaven, but nobody wants to die."

I am looking forward to having a cooperative and productive conversation on this topic today and to working with my colleagues on both sides of the aisle to come up with effective solutions to the problems addressed at today's hearing. Again, I would like to thank our witnesses for participating, and we look forward to your testimony.

At this time, I would ask unanimous consent that all members be allowed to submit statements and questions for the record. Without objection.

[The prepared statement of Hon. Nathan Deal follows:]

PREPARED STATEMENT OF THE HON. NATHAN DEAL, CHAIRMAN, SUBCOMMITTEE ON HEALTH

- The Committee will come to order, and the Chair recognizes himself for an opening statement.
- I am proud to say that we have two expert panels of witnesses appearing before us this morning that will help us examine the concerns raised by MedPAC, CMS, and others regarding the rapid growth of the use of imaging services in Medicare.
- Today's hearing will also provide a forum for witnesses to provide suggestions for how to determine what is proper versus improper growth of services, and how to best control for overutilization or misuse of services.
- Over the past few years, there has been rapid growth in the volume of imaging services paid under Medicare fee-for-service.
- In addition, the volume of imaging services has grown at almost twice the rate of all other physician services.
- Clearly, this level of growth is unsustainable.
- Some growth in use of imaging services is argued to be attributable to technological innovations that allow physicians to better diagnose disease. However, many observers argue that such growth may reflect overuse or misuse of imaging services.
- MedPAC has determined that spending for MRI, CT, and nuclear medicine has grown faster than for other imaging services.
- Accordingly, MedPAC has identified some factors that may contribute to the rapid growth in volume and intensity of imaging services, including:
    1. The possible misalignment of fee schedule payment rates and costs
    2. Physicians' interest in supplementing their professional fees with revenues from ancillary services
    3. Patients' desire to receive diagnostic tests in more convenient settings.
- In its March 2005 report to Congress, MedPAC recommended that Congress direct the Secretary to set standards for physicians interpreting or performing diagnostic imaging services.
- This is a recommendation I hope my colleagues on this subcommittee will carefully consider as we start to look at possible solutions to this problem.
- As my colleagues are no doubt aware, the Deficit Reduction Act of 2005 (DRA), included a provision that caps reimbursement for the technical component for imaging services performed in a physician's office at the hospital outpatient payment rate.
- Imaging services paid under the physician fee schedule involve two parts, a technical component and a professional component. The technical component of the payment covers the cost of the equipment, supplies, and non-physician staff.
- The DRA provision capping the technical component of physician payment for imaging services was intended to move toward payment neutrality across sites of service delivery.
- This provision takes effect January 1, 2007, and will save the Medicare program almost $3 billion over 5 years.
- Of course, many physician groups and industry stakeholders are pushing for a delay in the effective date of this provision.
- However, it is important to remember that these savings were a major financial component in preventing physicians from taking the 4.4% reduction in fee schedule payments that was scheduled to be implemented under the SGR formula for 2006.
- Unfortunately, few groups are offering legitimate offsets in order to pay for this requested delay in implementation.

- It kinda reminds me of the lyrics of an old Bobbie Gentry song, "Everybody wants to go to Heaven…but nobody wants to die."
- I am looking forward to having a cooperative and productive conversation on this topic today and to working with my colleagues on both sides of the aisle to come up with effective solutions to the problems addressed at today's hearing.
- Again, I would like to thank all of our witnesses for participating today, and we look forward to hearing your testimony.
- At this time, I would also like to ask for Unanimous Consent that all Members be allowed to submit statements and questions for the record.
- I now recognize the Ranking Member of the Subcommittee, Mr. Brown from Ohio, for five minutes for his opening statement.

MR. DEAL. I now recognize Mr. Pallone, who is standing in for our Ranking Member, for 5 minutes for his opening statement.

MR. PALLONE. Thank you, Mr. Chairman.

Without a doubt, recent advancements in medical imaging, such as computerized tomography, magnetic resonance imaging, and ultrasound have greatly improved physicians' ability to diagnose and treat patients. These technologies have the potential to improve health outcomes and lower healthcare costs by minimizing the need for invasive procedures and improve patient safety.

Over the past few years, however, we have seen an explosion in the use of medical imaging services. According to MedPAC's March 2005 report, between 1999 and 2002, the per beneficiary average annual growth rate in the use of fee scheduling imaging services was twice as high as the growth rates for all fee schedule services. Predictably, this type of growth has raised some eyebrows about the appropriate use of medical imaging technology.

Healthcare experts have identified several sources that are responsible for this growth, most of which has been attributed to the increased utilization in medical imaging in physician's offices as opposed to hospital outpatient departments where radiologists traditionally provided these services. One obvious benefit brought about by this change is that patients no longer have to be shuttled from one place to another simply to have an imaging study performed. This saves the patient both time and money. On the other hand, this change has also raised concerns that doctors are inappropriately using medical imaging services, whether it is a result of insufficient training or simply to boost their reimbursements. As a result, some experts have argued that as more and more doctors offer these types of services, Federal standards need to be put into place to ensure physicians are appropriately ordering imaging studies and patients have access to safe imaging services.

Such proposals are not without controversy. As MedPAC noted, and I quote, "It would be a major policy change for Medicare to require that physicians meet standards to receive payment for interpreting imaging

services." But clearly, physician groups remain skeptical. That is why I think it is important that we are having today's hearing, so that we can flesh out some of these ideas.

Unfortunately, Congress has already enacted significant payment reforms regarding medical imaging services without any debate. In the final hours before Congress passed the Deficit Reduction Act, a provision was slipped into the bill that would limit payment for medical imaging services provided in physician offices. Neither Congress, nor MedPAC, nor any other public forum has held a hearing or meeting on this proposal, and because there is no record, we don't know the impact this proposal will have on beneficiaries' access to medical imaging.

So Mr. Chairman, in the future, I would hope that you would call for regular order and ensure that this subcommittee and the full committee exercises their right to adequately review such policies before they go into effect. And while we are on the subject of regular order, I would like to just take a minute to highlight the fact that you still have not responded to our request, to the Democrats' request under Rule 9 under the Rules of the House to have another hearing held on implementation of Medicare Part D.

Mr. Chairman, it has been about 5 months since we have made this request formally, and we still haven't heard back. I think we deserve to hear from beneficiaries about their experiences with this program. For example, I am hearing more and more now about the donut hole as more and more people fall into the donut hole, you know, they contact my office and complain because they are not really aware of the impact of the donut hole. So there are problems, and some beneficiaries aren't getting the medications they need. Others aren't getting the subsidies they are entitled to, and we should be hearing from them.

So Mr. Chairman, I just wanted to say in conclusion, I want to thank you again for holding today's hearing. Ensuring the appropriate use of medical imaging services is an important topic, but so is the impact of Medicare Part D and its effect on beneficiaries. So I once again urge you to heed our requests and hold an additional hearing on that program and allow Democrats to call their own witnesses.

Thank you, Mr. Chairman.

MR. DEAL. We look forward to having another hearing on Medicare Part D and hear of the huge successes that that program has been, the great contributions that it has made to healthcare in this country, and we will honor that request.

MR. PALLONE. Thank you, Mr. Chairman.

MR. DEAL. I recognize Dr. Norwood for his opening statement.

MR. NORWOOD. Thank you very much, Mr. Chairman. I am very happy that we are exercising our jurisdiction over this issue. It has been

on the radar screen of others for some time, though they have done absolutely nothing about finding out the facts. They have just simply written some legislation. So I am delighted that our committee is beginning to look at this.

The New England Journal of Medicine recently identified medical imaging as one of the top 11 medical innovations of the past 1,000 years. Without hesitation, imaging has improved the health of all of our Nation by enhancing preventive and diagnostic medicine. And as imaging technology has progressed, local doctors have been able to provide these services. Has there been a growth in utilization of diagnostic imaging? Well, of course, yes, there has. Should this growth come as a surprise? It really shouldn't to anybody. We have an aging population, spent years encouraging preventative medicine. And like the rest of healthcare industry, innovation does not produce savings up front. But more than the quality of life issues involved, I will guarantee you that imaging saves money.

That said, in fact, I am a pretty good example of that. That said, is there some unnecessary imaging? Well, it only makes sense that there is. There is over-utilization in lots of places, frankly. Should we be concerned about any dramatic increase in spending? Well, as protectors of the taxpayer funds, we have to pay very close attention to that, and yes, we should be concerned. However, if we are worried about over-utilization, how do we specifically target that without simply cost shifting? Can we do that?

I know this is a general hearing, but we need to take a step back and reevaluate the payment adjustments in the DRA. We can say we don't want Part B to pay more than a hospital for the technical component of the same service, but has anyone asked how the payment systems differ? No. Or how beneficiary co-pays will be affected? No. Or how hospitals can spread costs? No. Hopefully, this committee is going to start asking those questions.

Wait times in hospital outpatient departments are too long already. If patients are left with fewer options, wait times are certainly going to increase dramatically. What if hospitals drop cost and drive private practices out? What will this do for competition, for patient care, especially in rural areas and for the taxpayer? And what at the end of the day have we done to address the real issue? Well, very little, I believe.

I hope this hearing will get to the heart of what we are trying to accomplish and see if what Congress has done matches that goal.

I thank Representative Pitts for his leadership, and agree, a moratorium on these adjustments is responsible, and until we get to a responsible policy, to do otherwise, because we haven't done our homework, is, in my mind, irresponsible.

Thank you again, Mr. Chairman, for this hearing. It is so very important. I look forward to the testimony of our witnesses, and yield back my time.

MR. DEAL. I thank the gentleman.

I now recognize the Ranking Member of the full committee, Mr. Dingell, for an opening statement.

MR. DINGELL. Mr. Chairman, thank you. Good morning to everybody.

Mr. Chairman, while addressing the issues about imaging services in Medicare is certainly important, my constituents talk to me much more about the Part D drug benefit than they do about imaging services. I note that the Minority members still have not had the opportunity as is afforded us under the Rules of the House to have a hearing on Medicare Part D drug benefit with witnesses of our choosing. I note that we have made that request. It is a matter of entitlement to us. It has not been honored. I am saddened by the inattention to the Rules of the House and the rights of the Minority. The Medicare program provides health security for more than 40 million beneficiaries today. Getting the addition of a new complicated benefit for prescription medicines where we have evidence that problems exist and improvements should be made, I believe that we must go into this matter with considerably more care, and that we must hear from all parties, not just administrative witnesses and representatives of the company and companies that are receiving financial gains from this program.

Today, the committee has chosen to focus on imaging services. That is an important question. Some of the problems that will be explored in today's hearing are yet another example of what goes wrong when legislation is cobbled together in haste and passed in haste. The Deficit Reduction Act, which remains under a legal cloud because of irregularities in its passage, made a number of changes to Medicare payments for diagnostic imaging services, changes that may have overreached in some areas and underreached in others. We know we are receiving complaints, but we do not know exactly what we have done or how well or poorly we have done it.

Payment cuts to meet a budget target are a blunt tool which may result in unintended consequences. Some of the witnesses today will explain to us how not all imaging services are alike, that changes appropriate for one set of services may not be appropriate for another type of service. We will also hear about quality standards to protect patient health and safety. I believe this is an issue that should be carefully explored by the committee. Our utmost concern should be to ensure that beneficiaries have access to the best quality of services, and we should not do anything which would create a solution which does not

achieve that purpose. That is an important purpose and it is a solution that the committee must address carefully.

I look forward to the testimony of witnesses here today, and to additional hearings on the Medicare program. It is rapidly being put into something of a mess.

Thank you, Mr. Chairman.

MR. DEAL. I thank the gentleman.

Mr. Pickering is recognized for an opening statement.

MR. PICKERING. Mr. Chairman, I thank you for holding this hearing. Please excuse my voice.

I want to just take a moment to talk about a bill that I introduced, the CARE bill, 129 sponsors, and I think it helps address some of the issues that will be raised in this hearing.

As we seek to improve the quality of care, reduce costs, and improve safety in the use of imaging, I think that the bill can help set the Federal standards for the education and the credentialing then implemented by the States. I am looking forward to hearing the panel today, and the testimony, and to see if the CARE bill and other things that we can do to address from the reimbursement side as well as the education side can begin making the progressive steps forward on how we should balance the great care that comes, the improved care that comes from imaging services, but to do it in a responsible way and to do it in the right way.

Mr. Chairman, I yield back. Thank you.

MR. DEAL. I thank the gentleman, and recognize Ms. Capps for an opening statement.

MS. CAPPS. Thank you, Mr. Chairman, and thank you for holding the hearing today. I look forward to the testimony of our witnesses. I am pleased that we have the opportunity to discuss the importance of preserving access to imaging services for Medicare beneficiaries, because I know there is great bipartisan support for maintaining the current system. I want to associate myself with two pieces of legislation, H.R. 5238, by my colleague Carol McCarthy from New York, who has asked me to ask for unanimous consent to insert a letter that she has written. She has written a letter to this subcommittee regarding the legislation she has introduced which would repeal the cuts altogether, so with permission, I ask for unanimous consent to have this letter inserted into today's proceedings.

MR. DEAL. Without objection.

[The information follows:]

July 18, 2006

Rep. Carolyn McCarthy Statement on the Use of Imaging Services: Providing Appropriate Care for Medicare Beneficiaries

The Committee on Energy and Commerce
Subcommittee on Health

Mr. Chairman, on February 8, 2006, President Bush signed into law the Deficit Reduction Act (DRA). This legislation made drastic cuts to several areas of health care. Our nation's imaging services will be placed at serious risk due to the cuts imposed by the DRA. It is impossible and irresponsible for this Committee to discuss Medicare beneficiaries' access to imaging services without addressing the effect of the DRA.

The cuts imposed as part of the DRA will lead to reimbursement reductions of upwards of 30-50 % for imaging services that patients and their physicians rely on to properly detect, diagnose and treat life-threatening conditions. Medicare beneficiaries will be denied life-saving technologies with many imaging providers being forced out of business, making it harder for patients to access imaging technologies. I have spoken with several radiologists in my district who will have to drastically scale back their operations or shut their doors altogether because of these cuts.

Beneficiaries will also face higher costs for care. In most instances, beneficiaries on fixed incomes who pay 20% co-pay for imaging services outside of the hospital will now be forced to pay up to 40% if directed to a hospital outpatient department for care. They will be left with no other option should their local radiology group be forced to shut down.

With fewer options for imaging services, our nation's Medicare beneficiaries will have to wait longer for medical care. Longer wait times increase the health risks for beneficiaries and may result in their needing more costly, invasive surgical procedures. This will increase the financial burden on our nation's already stressed healthcare system.

Reductions in reimbursements will make it more difficult for radiologists to purchase the most up-to-date equipment. Patients will have diminished access to state-of-the-art equipment and will be more likely to have their imaging studies performed with older equipment, affecting the quality of care they receive.

One would think that such substantial changes to a program would have occurred only after serious study and deliberation. However, these cuts were agreed to with little public deliberation by the U.S. House of Representatives. Yet they account for more than one-third of the Medicare cuts in the DRA. There has been no analysis of their impact on seniors' access to imaging services, and no assessment of potentially longer wait and travel times. In addition, no study has been conducted on the higher co-payments associated with receiving these services in other settings, like the hospital, which generally involves higher out-of-pocket costs, longer wait-times, and additional bureaucracy. Without Congressional action, these cuts will go into effect on January 1, 2007.

I am working with Rep. Pitts on HR 5704, the Access to Medicare Imaging Act of 2006. Our legislation places a simple two-year moratorium on the implementation of the cuts, and requires a comprehensive GAO study on patient access and service issues, relating to the availability and quality of imaging services in physician offices and imaging clinics, with special attention to seniors living in rural and medically underserved areas. The study will also examine the appropriateness of using the hospital outpatient department reimbursement rate as a proxy for all imaging services.

On January 1, 2007, our nation's Medicare beneficiaries will face an unnecessary risk. Congress has a responsibility to act now to ensure our seniors see no changes to their access to imaging services. That action begins with this Committee. I commend the Committee on holding this hearing and implore you to continue working to rectify the situation presented by the DRA.

CAROLYN McCARTHY
MEMBER OF CONGRESS

MS. CAPPS. I also want to acknowledge our colleague, Mr. Pitts, bill H.R. 5704, which I am sure will be part of our discussion today.

Along with my colleagues, I am deeply disturbed by the cuts to Medicare reimbursement for outpatient diagnostic imaging services, as I said, that were included in the Deficit Reduction Act. It is one of the very many reasons I voted against the bill, and I want to associate myself with the remarks of the Ranking Member of this full committee on many of the aspects of Medicare services that need to be addressed by this committee.

I am especially appalled that these cuts, upward of 30 to 50 percent, were enacted arbitrarily with little discussion, without any consideration for the effects of these cuts on patients, on real people. Logically, the reduction of reimbursements for outpatient imaging services will mean a reduction in the number of physicians who are going to be able to provide these services. This will mean Medicare beneficiaries traveling further to find providers who offer diagnostic imaging. It may leave beneficiaries themselves with no option but to obtain these services at hospitals where waits are longer and costs are often much higher. The logistical problems and higher costs may even result in patients opting

out of diagnostic imaging services altogether, and those people who are practitioners out in the field, out in the communities, know that this is a very real threat. There will be a lessening of the quality of healthcare we will be providing to America. Diagnostic imaging includes mammograms, ultrasounds, bone density screenings, MRIs, which are key to early detection of serious, fatal diseases. We are in an age where we know that early detection equals early treatment, which saves lives. Of course, it also saves money and great cost to our society, to families.

If we allow these cuts to go through, access to imaging services will be reduced, while wait times will be increased. The architects of these cuts did so in the name of cost saving. Well, you can be sure that the cost, as I mentioned, of treating a patient for advanced breast cancer certainly is going to be higher than the cost of a mammogram and early intervention. I am sure we are going to hear today even more about the innovation in diagnostic imaging, and I am sure that we will jointly praise the accomplishments of new technologies and techniques that allow us to detect disease early on, but let us not just sit here and listen. Let us discuss. This is our responsibility, the ways in which we can save access to these services and save lives.

I yield back.

MR. DEAL. I thank the gentlelady.

Mr. Pitts is recognized for an opening statement.

MR. PITTS. Thank you, Mr. Chairman. Thank you for convening this hearing today on such an important issue.

Mr. Chairman, I know the focus of this hearing is not just on the diagnostic imaging cuts included in Section 5102 of the Deficit Reduction Act, the DRA. We are also addressing the issue of over-utilization of imaging services, and its rapid growth in the last few years.

Regarding over-utilization, I am troubled by MedPAC's March 2005 report on the skyrocketing use of imaging services, and its conclusion that increased use of these services is not linked to better health outcomes for patients. I am also interested in CMS's and MedPAC's recommendations on quality standards for imaging equipment and radiology technicians, image quality, patient safety, and interpreting physicians.

However, I would also like to discuss the impact of these cuts. Section 5102 of the DRA will result in drastic cuts in reimbursement, upwards of 30 to 50 percent for the technical component of critical imaging services provided in physician's offices and independent imaging centers. No analysis has been conducted regarding the impact that this change in policy will have on Medicare beneficiaries' access to imaging services in a setting that allows for more timely diagnosis and treatment.

Barring any statutory change, these cuts will go into effect on January 1 of next year, and that is why I have introduced a common sense, fiscally responsible bill, H.R. 5704, the Access to Medicare Imaging Act of 2006, which would simply delay implementation of these cuts by 2 years, to January 1, 2009. This delay will give the GAO time to conduct a study, required by the legislation, on the impact these cuts would have on patient access and service issues, with special attention to rural and medically underserved areas. H.R. 5704 enjoys bipartisan support from over 55 cosponsors, including 12 members of this subcommittee--six Republicans and six Democrats. Additionally, my bill is supported by the Access to Medical Imaging Coalition, which represents more than 75,000 physicians and providers and patients, as well as medical imaging manufacturers who employ tens of thousands of workers. In fact, several of today's witnesses, Dr. Donald Rucker, testifying on behalf of the National Electrical Manufacturers Association, Dr. Arl Van Moore from the American College of Radiology, and Mr. Robert Baumgartner, testifying on behalf of the National Coalition of Quality Diagnostic Imaging Services, represent organizations which are a part of this coalition.

Mr. Chairman, I look forward to hearing from our distinguished witnesses and learning their views and recommendations on these important issues. I would like to extend a special welcome to Donald Rucker from Siemens Medical Solutions, USA, and a resident of my home State of Pennsylvania.

I yield back the balance of my time.

MR. DEAL. I thank the gentleman.

Mr. Green is recognized for an opening statement.

MR. GREEN. Thank you, Mr. Chairman, for holding the hearing on imaging services on Medicare. I would like to welcome our first panel today, and the following panel.

There is no question the volume of imaging services increased dramatically over the last couple of years. In fact, from 1999 to 2003, imaging volume grew twice as fast as other physician services. The potential explanations for this growth are numerous: quality of imaging technology improving so it is being utilized more; more physicians investing in imaging technology so they can diagnose diseases right in their offices; and there is a growing trend among physicians investing in freestanding imaging facilities which can lead to increased referrals.

While there are a number of plausible explanations, they are accompanied by even more questions. Are the imaging services being delivered in the most efficient manner? Are the payment rates appropriate? Are patients better off, that is, is the volume growth in

imaging services leading to quicker detection and treatment of disease? Does increased utilization necessarily mean over-utilization?

Despite all these questions, conferees and the Deficit Reduction Act rush to include payment cuts for imaging services without the benefit of stakeholder input or an in-depth analysis of the issue. In fact, the provision wasn't even in the House or the Senate versions. It was a last minute inclusion in the conference report. That is why I am a cosponsor of Congressman Pitts' H.R. 5704 to delay these cuts for 2 years so we will have time to analyze its impact. This policy, which is set to go into effect in January of 2007, will have tremendous impact on physicians offering imaging services. Those utilizing ultrasound for guidance procedures will see their reimbursement rates fall by approximately 35 percent. Reimbursements for PET or CT scans used to diagnose cancer would be reduced by 50 percent. Can we estimate the effect of this policy on the physician, but what impact will it have on the Medicare beneficiaries, the very folks who depend on this technology for their healthcare? I know personally, Mr. Chairman, that a lot of physicians use imaging particularly in our effort on aortic aneurysms to screen for those. If this policy leads physicians to term if they one, cannot afford to offer these services or two, can't afford to accept Medicare beneficiaries, we find ourselves with an access problem. Our office hears from Medicare beneficiaries who already find it difficult to make it to the doctor for their appointment. What effect would this policy have on them if they are forced to schedule multiple appointments for imaging?

We also need to look more closely at the quality of imaging services and how the proliferation of non-radiologist imaging is affecting quality, if at all. There hasn't been enough analysis of these issues and I am concerned that the Deficit Reduction Act may be cutting the meat and not just the fluff.

To look deeper into the issue, I, like I said, joined my colleagues on this subcommittee in cosponsoring Mr. Pitts's legislation. I would also like to see more analysis of the appropriateness of any imaging utilization. I look forward to hearing from our witnesses in the amounts of charges of over-utilization.

I yield back my time.

MR. DEAL. I thank the gentleman.

Dr. Burgess is recognized for an opening statement.

MR. BURGESS. Thank you, Mr. Chairman. I also want to thank you for holding this hearing today.

Medical imaging is, of course, extremely important technology. It is entering into its second century of existence. We have seen embellishments of old technology and we see new technology emerging almost daily in the challenges to adequately reimburse for both.

In my practice, the use of ultrasound was pretty much a standard practice of medicine in OB/GYN. OB/GYN practices are kind of unique, and ultrasound is ubiquitous to our ability to deliver care to our patients. In fact, probably 90 percent of OB/GYN practices across the country possess their own in-office ultrasound machines. It is analogous to the use of a stethoscope in clinical practice.

New modalities allow doctors to identify and diagnose disease in a manner that was unthought of even as much as 2 years ago. I hope this hearing today will help us understand where medical imaging technology is assistive and where there may be opportunities to gain efficiency and subsequent savings in the Medicare program.

I am pleased that we have today with us Dr. Douglas Laube, the President of the American College of OB/GYN. I have been a fellow of the College for nearly 25 years, and know very well the fine work of this specialty organization. Dr. Laube chairs the Department of OB/GYN at the University of Wisconsin Medical School in Madison, and he also holds a medical education degree from the University of Iowa. He has been teaching and training OB/GYNs since the mid-'70s. He has chaired the Council on Residency Education for OB/GYNs, as well as the National Board of Medical Examiners.

I am also pleased to welcome from Dallas, Dr. Landis K. Griffeth, M.D., Ph.D., who is the Director of Nuclear Medicine at Baylor University Medical Center in Dallas. He is also the National Medical Director for Positron Emission Tomography at U.S. Oncology.

Mr. Chairman, I also just want to take one moment, and other Members have talked about issues with the coverage gap in the Medicare prescription drug program. I would point out, in my home State of Texas, there are five companies that offer generic medicine coverage in the gap. There is one company that offers both generic and branded medicines in the gap. I think it is a shame that other members didn't take the time to educate their constituents about these very valuable programs. They are not necessary for every senior on Medicare, but certainly, they are valuable and assistive to many patients who take a variety of medications to meet their healthcare needs.

With that, Mr. Chairman, I will yield back.

MR. DEAL. I thank the gentleman.

Ms. Myrick is recognized for an opening statement.

MS. MYRICK. Thank you, Mr. Chairman. I look forward to the discussions all the rest today, and welcome all of our panelists, but I especially wanted to recognize Dr. Arl Van Moore, who is a friend and a constituent from Charlotte, North Carolina. Dr. Van Moore has over 20 years experience as a radiologist, and he can share not only his expertise,

but his real world experience in dealing with the payment system in Medicare. We are glad you are here today.

We haven't really gotten our arms around the growth in the imaging services in Medicare, and a lot of stakeholders don't think that the technical cap in the DRA was the most effective way to do so. Particular specialties may be affected more than others, and it is not clear that the hospital outpatient codes are always accurate when it comes to reflecting actual cost.

With that said, we need to recognize the scope of the problem. It is not a bad thing that Medicare beneficiaries are using more MRIs, CT scans, et cetera. Imaging can detect disease and save lives, and many of us know firsthand. I am a breast cancer survivor, and I had three mammograms and five doctors examined me, and they all told me I was fine. It wasn't until I had an ultrasound that they found my tumor, which saved my life. I am very thankful for that. Nevertheless, doctors have a responsibility to use these technologies appropriately, and we have a responsibility to the taxpayers to make sure that the Medicare payment structure makes sense.

So I hope this hearing is going to give us some direction going forward, and I want to say thanks again to both panels.

Mr. Chairman, I yield back my time.

MR. DEAL. I thank the gentlelady.

Mr. Ferguson is recognized for an opening statement.

MR. FERGUSON. Thank you, Mr. Chairman. Thank you for convening this very important hearing concerning an issue that is important to physicians and also to patients who benefit from imaging services.

There is no doubt that there have been tremendous advances in imaging over the last decade, but along with those advances have come increases in utilization of services and subsequently, costs to Medicare and the healthcare system. The payment policy included in the DRA for medical imaging procedures has raised a lot of concern from stakeholders, and I believe for good reason. As I understand it, the policy says that with regard to the technical component, more cannot be paid under the Medicare physician fee schedule for a medical imaging procedure done in a physician's office than what is paid if that procedure were done in the hospital outpatient setting. This policy appears to make the assumption that the hospital outpatient perspective payment system more accurately reflects the true cost of a medical imaging procedure. If this is the case, then I am puzzled as to why in those cases where the hospital outpatient payment is higher than what is paid in a physician office for the same medical imaging procedure that this policy does not increase the payment in the physician office setting. This strikes me as a

case where the OPPS is only more accurate when it pays less than a Medicare physician fee schedule, but not accurate when it pays more. This reminds me of the old saying "Tails, I win, heads, you lose."

I hope that the witnesses from CMS and MedPAC today will shed light on what I see as a troubling aspect of the policy included in the DRA. It is vital that we spend the time to get this right and that is what this hearing is about.

I look forward to hearing from our panelists today, and to hear their proposals and ideas on how to control and manage utilization of imaging services properly. These are important issues to discuss, but I believe they must be discussed under the context of what was done in the Deficit Reduction Act. Above all, I look forward to working with you, Mr. Chairman, to craft a policy that can more accurately reflect proper payment for these services without encouraging over-utilization.

Thank you very much, Mr. Chairman. I yield back.

MR. DEAL. I thank the gentleman.

[Additional statements submitted for the record follow:]

PREPARED STATEMENT OF THE HON. JOE BARTON, CHAIRMAN, COMMITTEE ON ENERGY AND COMMERCE

Good morning. I would like to welcome all of our witnesses here today. I look forward to hearing your perspectives on a troubling trend in Medicare: the year-in and year-out growth in spending for imaging services ordered by doctors.

Physician spending for imaging services has more than doubled in the past five years, accounting for a significant portion of total increased physician spending each year. Why is this so? What accounts for this rapid growth? These are questions that are front and center for today's hearing.

The current rate of Medicare spending on Part B services is simply not sustainable. Overall, Part B spending increased by 11 percent in 2005, while expenditures for physicians' services alone grew by 10 percent. According to CMS, such rapid growth is driven by more use of more intensive physicians' services, including imaging services, among others. In addition, CMS has found that use of many of these services varies substantially across practices and geographic areas without any clear associated impact on patient health.

More importantly, overuse or misuse of physician services has a direct impact on the health and well-being of the patient. Such use also has a direct impact on the costs of Medicare Part B services, reflected by the copayments beneficiaries must pay for services that may not be necessary or inappropriate. Rapid growth in utilization of services spending on Part B services also causes the Part B premium to rise each year. It is simply not fair for our seniors to shoulder the costs of improper growth in physician spending.

We need to better understand what drives the growth. Is it medically beneficial or misuse of technology, or both? I understand that some growth may be attributed to technological innovations that allow physicians to better diagnose disease. To this extent, I applaud physicians for seeking out the best, most effective care available for our seniors. However, it is also my understanding that the rapid growth in volume and intensity of imaging services may be driven by the possible misalignment between fee schedule payment rates and actual costs. If that is true, how do we control for this? We must also examine the effect of defensive medicine on the increased use of these services.

These are some of the questions I have for our witnesses today as we begin to look at one area of physician spending that continues to grow unsustainably each year. As we look ahead to how to best address problems with the underlying physician payment system, one important consideration is how to best control for overutilization of services that are not necessary or possibly harmful to patients. The SGR was designed to control for such overuse of services, but it appears it has not done the trick. As we look at building a new physician payment system, questions about how to control physician spending must be addressed. Today's hearing is an important first step at looking at this issue.

I want to thank Chairman Deal for calling this hearing, and reiterate my thanks to all the witnesses for coming today. I look forward to their testimony.

PREPARED STATEMENT OF THE HON. ANNA ESHOO, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF CALIFORNIA

Thank you, Mr. Chairman.

Medical imaging has transformed the way modern medical care is delivered. The successes of medical imaging technologies are due in part to the research conducted by the National Institute of Biomedical Imaging and Bioengineering at NIH. This Institute was established in 2000 by the *National Institute of Biomedical Imaging and Bioengineering Establishment Act,* which then-Representative Richard Burr and I sponsored.

The benefits and promise of medical imaging are immense. Imaging technologies can often detect critical illnesses at their most curable stage when they are also less costly to treat. Less-invasive care, fewer complications, shorter hospital stays, and better patient management have also fostered greater efficiency and savings throughout the healthcare delivery system.

Medical imaging is an essential tool of modern medicine. Physicians rate CT and MRI as the most important medical innovations in providing quality care for their patients.

In the case of aging populations, imaging is particularly useful in preventing patients from undergoing invasive surgeries, avoiding extended periods of recuperation or disability.

I'm eager to hear the testimony of our expert witnesses today who will explain the new and emerging imaging technologies that will help revolutionize the way health care is delivered.

The *Deficit Reduction Act (DRA)* included severe cuts in payments for medical imaging in the Medicare physician fee schedule. These cuts were not included in either the House or Senate-passed versions of the *DRA* bill, but were added to the Conference report at the last-minute in order to increase revenue.

Today, imaging comprises roughly one-tenth of Medicare spending, yet the cuts to imaging in the *DRA* comprise roughly one-third of the total Medicare savings in the bill, a highly disproportionate and unfair slice of the pie. Specific categories of imaging services fare no better:

- Reimbursement for ultrasound guidance procedures, performed as part of a minimally invasive biopsy for the diagnosis of breast cancer, would be reduced by 30%.
- Reimbursement for PET/CT exams used to diagnose cancerous tumors and determine the effectiveness of cancer treatment would be reduced by upwards of 50 percent.
- Reimbursement for bone densitometry studies necessary for the diagnosis of women at risk for osteoporosis, a recently enacted Medicare screening benefit, would be reduced by over 40%.

- Reimbursement for MRIs of the head used to detect the location of aneurysms would be reduced by 42%.

Because of the increased risk of disease and illness in aging populations, these cuts will affect the ability of Medicare beneficiaries to receive potentially life-saving imaging procedures and diminish the quality of care patients receive.

The devastating effects these cuts will have are unfounded and unacceptable. That's why I urge my colleagues to join me in supporting H.R. 5704, the *Access to Medicare Imaging Act of 2006.* This bipartisan bill places a 2-year budget-neutral moratorium on the cuts while GAO does a study on the impact of these provisions.

Thank you, Mr. Chairman, I look forward to hearing from the witnesses.

MR. DEAL. I believe all the opening statements have now been concluded. It is my pleasure to introduce our first panel. First of all, Mr. Herb Kuhn, who is the Director of the Center for Medicare Management, that's CMS. Mr. Glenn Hackbarth, who is the Chairman of the Medicare Payment Advisory Commission. Gentlemen, we are pleased to have both of you here. Your written testimony has been made a part of the record. We would ask you to use your 5 minutes to summarize that testimony for us today.

Mr. Kuhn, we will start with you.

STATEMENTS OF HERB KUHN, DIRECTOR, CENTER FOR MEDICARE MANAGEMENT, CENTERS FOR MEDICARE AND MEDICAID SERVICES, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES; AND GLENN M. HACKBARTH, J.D., CHAIRMAN, MEDICARE PAYMENT ADVISORY COMMISSION

MR. KUHN. Chairman Deal, Representative Pallone--

MR. DEAL. Turn your microphone on, please.

MR. KUHN. Thank you.

Chairman Deal, Representative Pallone, members of the subcommittee, thank you for the opportunity to discuss with you some of the changes in payment for imaging services under the Medicare physician fees schedule. Spending for these services has risen dramatically in the past several years, prompting a number of recommendations by MedPAC, many of which we have implemented, and of course, the subsequent actions we have heard about today by Congress to address the increased spending associated with the rise in both the volume and intensity of these services. We want to ensure that Medicare's payment mechanisms encourage clinically appropriate use of resources and the highest quality of care, and we welcome input from this subcommittee, the physician community, and others interested in this issue.

Medicare's spending for imaging services has grown rapidly. As we have heard, it is nearly doubled over the last 5 or 6 years. New information from CMS shows that between 2000 and 2005, spending for imaging services paid under the physician fee schedule doubled from $6.6 billion to $13.7 billion, an average annual rate growth of 15.7 percent. This compares to the overall annual growth in physician services of 9.6 percent. We also see more extensive geographic variation in spending for imaging services than for other physician services. MedPAC has also found similar findings in terms of variation. This significant variation in use of imaging services, even among contiguous States, appears to be with no evidence towards better outcomes for the patients, as we see right now. The rapid increase in Medicare spending for imaging services, coupled with extensive geographic variation in their use, raises question about whether such growth is appropriate and whether all imaging services are used appropriately as well.

Currently, we estimate that spending for physicians grew by 10 percent during 2005. Seven percentage points of this growth is attributable to the volume and intensity of physician services, a rate that is in line with the past few years. In March, we estimated that the increase in spending for imaging accounted for 27 percent of the increase in physician-related spending. This level of growth is adding additional pressure to the sustainable growth rate system.

As noted in last week's mid-session review of the budget, growth and spending for physician services is a notable contributor to the increase in the Part B premium, which is now projected to be $98.40 in 2007, an increase of almost $10 from the 2006 Part B premium. Rapid increases in spending for imaging services contributes significantly to the increase in spending for physician services, and thus help also fuel the Part B premium.

To address this situation, CMS, as I indicated earlier, has taken several steps. First, in response to a MedPAC recommendation, we added nuclear medicine services to the list of services for which a physician is prevented from making a self-referral under Medicare and Medicaid under the STARK law.

Second, in the physician fee schedule rule in 2006, we indicated that we would look at multiple imaging procedures, and we looked at 11 families of related codes that are performed on contiguous body parts. Basically what we did was make a particular proposal and a recommendation that we would reduce the subsequent procedure by 50 percent, 25 percent this year and an additional 25 percent next year. Under requirements for budget neutrality, we took the step of increasing payments for all 2006 physician fee schedule services in order to balance out those reductions.

The Deficit Reduction Act of 2005 contains two major provisions, as we have heard about today. The first one is on the contiguous body part recommendation that we made on last year's rule, dealing with the technical component of that one. Instead of being budget neutral, there are savings associated with that and we will take those savings as part of the DRA. The second, of course, as we have heard is the provision dealing with the OPPS cap, and therefore reducing physician imaging services in physician offices to the level that is in the OPPS payment rate. Basically a side neutral payment system is what was envisioned in that particular legislation.

We realize that significant technology advances in imaging capabilities have made a difference in clinical practice and the lives of patients. I think this committee has well-articulated that in their openings statements. However, we want to ensure that our payment system rewards clinically appropriate care and does not provide inappropriate incentives for growth in volume and intensity of services with limited clinical benefit. To that end, CMS will continue to work with the physician community, other interested parties, and of course, this subcommittee and others in Congress as we refine our payment systems for medical imaging.

I thank the subcommittee for this time, and I look forward to your questions.

[The prepared statement of Herb Kuhn follows:]

PREPARED STATEMENT OF HERB KUHN, DIRECTOR, CENTER FOR MEDICARE MANAGEMENT, CENTERS FOR MEDICARE & MEDICAID SERVICES, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

Chairman Deal, Representative Brown, distinguished members of the Subcommittee; I thank you for the opportunity to discuss with you some of the changes in payment for imaging services under the Medicare physician fee schedule. Spending for these services has risen dramatically in the past several years, prompting a number of recommendations by the Medicare Payment Advisory Committee (MedPAC), some proposals by CMS, and subsequent actions by the Congress to address the increased spending associated with the rise in the volume and intensity of these services. We want to insure that Medicare's payment mechanisms encourage clinically appropriate use of resources and the highest quality of care, and we welcome input from you, the physician community, and other interested parties as we do so.

Background

Medicare spending for imaging services has been growing rapidly. Between 2000 and 2005, spending for imaging services paid under the physician fee schedule more than doubled from $6.6 billion to $13.7 billion, an average annual growth rate of 15.7 percent. This compares to an annual growth rate of 9.6 percent for all physician fee schedule services.

As we noted in a letter to MedPAC on April 7, 2006 (see table 1), while imaging services represented an estimated 14 percent of 2005 spending included in the sustainable growth rate calculation (SGR-related spending), they represented 27 percent of the total

increase in such spending between 2004 and 2005. Spending for imaging services contributed 2.3 percentage points of the 8.5 percent increase in SGR-related spending reported in our April 7th letter to MedPAC. No other service category affects the increase in SGR-related spending so disproportionately.

Table 2 shows growth rates for imaging services for calendar years 2003, 2004 and 2005, overall and for four subcategories of imaging services: standard imaging, advanced imaging, echography, and imaging procedures. Overall, spending for imaging services grew at 16 percent per year for each of these years.

The "standard imaging" category includes services such as chest x-rays, contrast gastrointestinal imaging, nuclear medicine procedures, and PET scans. Spending for standard imaging procedures increased by an estimated eight percent during 2005 and by 43 percent from 2003 to 2005. This category represents an estimated five percentage points of the 14 percent share that imaging represents of 2005 SGR-related spending. This category contributes an estimated 0.4 percentage points to the 2.3 percent increase in imaging spending and to the 8.5 percent increase in SGR-related spending.

Spending for the "advanced imaging" category, comprised largely of CAT scans and MRI procedures grew by 25 percent during 2005 and 82 percent from 2003 to 2005. This category represents an estimated five percentage points of the 14 percent share that imaging represents of 2005 SGR-related spending. This category contributes an estimated 1.3 percentage points to the 2.3 percent increase in imaging spending and to the 8.5 percent increase in SGR-related spending.

The "imaging procedures" category includes services such as cardiac catheterization, fluoroscopy, and 3-D holographic reconstruction. Estimated spending for the imaging procedures category of services increased by 20 percent during 2005 and 47 percent from 2003 to 2005. This category represents an estimated one percentage point of the 14 percent share that imaging represents of 2005 SGR-related spending. This category contributes an estimated 0.1 percentage points to the 2.3 percent increase in imaging spending and to the 8.5 percent increase in SGR-related spending.

Estimated expenditures for the "echography" category of services increased by 17 percent during 2005 and grew 49 percent from 2003 to 2005. This category represents an estimated three percentage points of the 14 percent share that imaging represents of 2005 SGR-related spending. This category contributes an estimated 0.6 percentage points to the 2.3 percent increase in imaging spending and to the 8.5 percent increase in SGR-related spending.

No matter how one looks at it, Medicare spending for imaging services under the physician fee schedule is growing very rapidly and more rapidly than spending for other services tracked under the SGR system. While MedPAC suggested that some imaging services have shifted from being furnished in facilities, such as hospitals, to physicians' offices, MedPAC also observed that about 80 percent of the growth in the volume and intensity of these services is unrelated to a shift in setting. The rapid increase in Medicare spending for imaging services, coupled with extensive geographic variation in their use, raises questions about whether such growth is appropriate and whether all imaging services are used appropriately.

Last week the Administration released the Mid-Session Review of the Budget. Part B spending was up from prior estimates. Spending for physicians' services is estimated to have increased by 10 percent during 2005, and 7 percentage points of this growth was attributable to the volume and intensity of physicians' services. The volume and intensity of physicians' services has increased at rates of 6 to 7 percent per year for the past few years. Growth in spending for physicians' services has been a notable contributor to the increases in the Part B premium. Rapid increases in spending for imaging services contribute significantly to the increase in spending for physicians' services.

MedPAC Recommendations and the 2006 Medicare Physician Fee Schedule

Limiting Physician Self-Referrals

Section 1877 of the Social Security Act, known as the "Stark Law," prohibits a physician from making a referral for certain designated health services, payable by Medicare or Medicaid, to an entity with which the physician or one of his/her close family members has a financial relationship, unless one of a specific list of exceptions applies. Among other things, the statute defines designated health services to include "radiology services, including magnetic resonance imaging, computerized axial tomography and ultrasound services" and "radiation therapy services and supplies".

In its March 2005 report to Congress, MedPAC recommended inclusion of nuclear medicine services in a list of services for which a physician is prevented from making a self-referral under Medicare and Medicaid.

In the notice of proposed rulemaking (NPRM) for the 2006 physician fee schedule, we pursued this MedPAC recommendation and proposed including diagnostic and therapeutic nuclear medicine procedures under the designated health services categories for radiology and certain other imaging services, and radiation therapy services and supplies, respectively. After considering comments on this proposal, we finalized this policy in the 2006 physician fee schedule final rule. To provide time for the industry to adjust, we deferred the effective date of this policy until January 1, 2007.

Despite this change, most physicians in groups that own imaging equipment will be able to continue to make self-referrals for imaging services within their own group by qualifying for one of the broader exceptions to the law -- the "in-office ancillary services" exception. Thus, defining a given service as a designated health service and making it subject to the prohibition against self-referrals does not mean that it will no longer be delivered pursuant to a self-referral in all cases. This change in policy will therefore be only partially effective in addressing growth in the volume and intensity of that particular type of imaging services.

Taking Efficiencies into Account

In general, payment amounts under the Medicare physician fee schedule are calculated using the assumption that each service is furnished independently. Prior to 2006, fee schedule payments for imaging did not take into account efficiencies that occur when multiple services are furnished sequentially. For example, the fee schedule amounts for CT scans of the pelvis and abdomen are established as if each imaging service were the only one being furnished to a beneficiary during a given encounter. The March 2005 MedPAC report recommended reducing the technical component of fee schedule payments for multiple imaging services performed on contiguous body areas. The technical component of an imaging service captures the administration of the test; it does not include the professional interpretation of the test.

In the NPRM for the 2006 physician fee schedule, we proposed revising payment amounts for the technical component of certain imaging services in order to more accurately reflect the economies of subsequent procedures when multiple imaging services are furnished within one of 11 families of imaging procedures on contiguous body parts in the same session with the patient. Specifically, we proposed establishing payment amounts at 50 percent of the technical component of any subsequent imaging procedures performed on a single patient during a single session if the initial and subsequent services were performed on contiguous body parts within one of 11 families of imaging procedure codes. The 50 percent figure was based on our view that most of the clinical labor and supplies are not furnished twice. In response to comments on the proposal, we indicated in the final rule for the 2006 physician fee schedule that we planned to phase in the 50 percent reduction over two years, beginning with a 25 percent reduction in 2006. However, we indicated that we would continue to accept comments and any supporting information from the public, and consider whether it would be

appropriate to modify the 50 percent payment reduction policy scheduled to take effect for 2007.

The statute requires that we make physician fee schedule changes, such as the multiple imaging policy, in a budget-neutral fashion relative to overall physician fee schedule expenditures. If changes result in increased spending compared to spending that would occur without them, then a reduction in payments is needed to achieve budget-neutrality. Similarly, if changes result in decreased spending compared to spending that would occur without them, an increase in payments for all services is needed to achieve budget-neutrality. Since the multiple procedure policy resulted in a decrease in spending, we increased payments for all 2006 physician fee schedule services in order to achieve budget-neutrality.

Assumptions Used in Setting Fee Schedule Payments for Imaging

The methodology for determining practice expense relative values for services that involve equipment such as that used in furnishing imaging services involves assumptions about how frequently the equipment is used. In its September 30, 2005, comments on the NPRM for the 2006 physician fee schedule, MedPAC raised concerns about the equipment utilization assumption for imaging services.

CMS's method of calculating payments for the technical component of imaging services assumes that imaging equipment is used only 50 percent of the time. MedPAC suggested that imaging equipment could be assumed to be used more than 50 percent of the time, given the rapid growth in imaging services. In its June 2006 report to Congress, MedPAC continued its analysis of the equipment utilization assumption for imaging services and indicated: "If a machine is actually used most of the time, its cost is spread across more units of service, resulting in a lower cost per service than if it were operated half the time. Such equipment is currently overvalued by CMS". In its June 2006 report to Congress, MedPAC also raised questions about the estimates of the cost of capital to purchase equipment such as imaging equipment.

MedPAC argues that the upshot of CMS's equipment utilization and capital cost assumptions is that Medicare payments for imaging services are too high. The June 2006 MedPAC report indicates, "increasing the equipment use assumption and lowering the interest rate assumption would reduce PE payment rates for services like CT and MRI studies." The report contains a table with examples of alternative assumptions; payments for imaging services could be reduced by 40 to 50 percent with alternative assumptions. However, data to substantiate alternative equipment utilization assumptions are not available.

The Deficit Reduction Act of 2005

The Deficit Reduction Act of 2005 contains two major provisions that directly affect Medicare payments for imaging services.

Eliminating Budget-Neutrality for the Multiple Imaging Policy

Subsequent to the publication of the final rule for the 2006 Medicare physician fee schedule, section 5102(a) the Deficit Reduction Act (DRA) of 2005 exempted the multiple imaging savings from budget-neutrality. In other words, the DRA requires that, for the 2007 physician fee schedule, we do not offset the savings attributable to the multiple imaging payment reduction policy for 2006 and 2007 by increasing payments for other physician fee schedule services in 2007.

The Hospital Outpatient Department Cap on Physician Fee Schedule Imaging Payments

DRA establishes caps on physician fee schedule payments for certain imaging services at the payment levels established in Medicare's hospital outpatient prospective payment system (OPPS). The provision requires that Medicare not pay more under the

physician fee schedule than Medicare would pay under the OPPS for furnishing the same imaging procedure. This policy applies to the technical components of imaging services including X-ray, ultrasound, nuclear medicine, MRI, CT, and fluoroscopy services. A physician's interpretation of the test for which Medicare will pay a separate fee is not affected by the provision. Screening and diagnostic mammograms are exempt from this policy change. This policy will begin in 2007.

An example of how this policy works can be seen in the case of an MRI of the brain or an MRI of the abdomen. In 2006, the Medicare physician fee schedule payment is $903 for the technical component of either of these MRIs. At the same time, Medicare pays hospital outpatient departments $506 for the exact same test. Thus, Medicare is paying almost $400 or 78 percent more for doing these MRI imaging tests purely depending on whether the test is performed in a hospital outpatient department or in a physician's office (or other setting paid under the physician fee schedule). These comparisons do not include a physician's interpretation of the test for which Medicare will pay a separate fee.

Among imaging procedures, there is little consistency in the percentage by which payments for the technical component under the physician fee schedule exceed payments under the OPPS. The percentage difference varies by procedure. We are still working on the proposed rules for 2007 for both OPPS and the physician fee schedule. The fee schedule NPRM will contain the specific impacts of the DRA imaging provision.

Conclusion

Medicare spending for imaging services has experienced very rapid growth. In addition, through 2006, Medicare is often paying significantly larger amounts under the physician fee schedule than the OPPS for the same imaging service furnished in the two different settings. MedPAC's analysis of assumptions used to calculate payment amounts indicates payments for imaging services under the physician fee schedule are too high. However, there is a lack of information to support alternative assumptions.

We will implement the DRA provisions through notice and comment rulemaking. NPRMs for OPPS and the physician fee schedule are expected to be published this summer. Final rules will be published this fall and will be effective for services furnished on or after January 1, 2007.

We realize that significant technological advances in imaging capabilities have made a difference in clinical practice and in the lives of patients. However, we want to ensure that our payment systems reflect clinically appropriate care and do not provide inappropriate incentives for growth in volume and intensity of services with limited clinical benefit. To that end, CMS will continue to work with the physician community, other interested parties, and the Congress as we refine our payments for medical imaging. I thank the Subcommittee for its time and look forward to answering any questions you might have.

Table 1: Spending Growth by Type of Service from 2004 to 2005

Type of Service	Growth Rate	Percent of Spending	Contribution to Increase	Percent of Increase
Evaluation and Management	7%	37%	2.6%	31%
Procedures	9%	26%	2.5%	29%
Imaging	16%	14%	2.3%	27%
Lab and Other Tests	11%	12%	1.3%	15%
Drugs (under the SGR)	-3%	9%	-0.3%	-4%
Other Services	20%	1%	0.3%	4%
Total	8.5%	100%	8.5%	100%

Source: Table 2 in April 7, 2006 letter from Herb Kuhn, Director, Center for Medicare Management, CMS to Glenn M. Hackbarth, Chair, MedPAC

Table 2: Spending Growth for Four Categories of Imaging Services

Types of Imaging Services	2003 Growth Rate	2004 Growth Rate	2005 Growth Rate	2003-2005 Growth	Percent of 2005 Spending	2005 Contribution to Increase
Standard Imaging	15%	15%	8%	43%	5%	0.4%
Advanced Imaging	20%	21%	25%	82%	5%	1.3%
Echography	13%	13%	17%	49%	3%	0.6%
Imaging Procedure	10%	11%	20%	47%	1%	0.1%
Total Imaging	16%	16%	16%	56%	14%	2.3%

Source: From Table 6 in April 7, 2006 letter from Herb Kuhn, Director, Center for Medicare Management, CMS to Glenn M. Hackbarth, Chair, MedPAC

MR. DEAL. I thank the gentleman.

Mr. Hackbarth.

MR. HACKBARTH. Thank you, Chairman Deal, and Ranking Member Pallone, other members of the committee. It is good to see you again.

As has been discussed already, Medicare expenditures for diagnostic imaging have been increasing rapidly, and having passed out to you two graphs from our testimony that illustrate this point, the first graph shows that imaging services per Medicare beneficiary increased 62 percent from 1999 to 2004. This compares to 31 percent increase for all fee schedule services.

This 62 percent increase is an increase in what we refer to as the volume and intensity of imaging services. In other words, it does not include any price effect. This is just the increased utilization and complexity of the services provided. Roughly about 20 percent of this increase in volume and intensity relates to the migration of services from hospital outpatient departments into physician offices.

The second graph that you have in front of you shows that there are substantial variations in growth rates of different types of imaging services, with advance imaging in nuclear medicine leading the way with the most rapid increases.

The question of the day, of course, is whether growth in imaging is a good thing or a bad thing. The answer is it is some of each. The growth in imaging is due to a variety of different factors.

First of all, as many members of the committee have pointed out, there have been tremendous improvements in the quality of imaging techniques. Improvements that lead to better healthcare for patients may result in reduced expenditures in some individual cases for other services. In addition to that, at least some types of equipment have also been falling in price and shrinking in size, making it easier to move that equipment from hospital settings or other institutional settings into physician offices. Those convenient locations, in turn, make it easier for physicians and patients to do more imaging. Some physicians also look to imaging to provide some protection against malpractice suits, a widespread concern among physicians. And of course, some physicians also see income from imaging as a supplement to their professional fees, particularly since misalignment between the fees paid and actual cost may have created some unusual profit opportunities.

From MedPAC's perspective, two types of research suggest that imaging is worthy of your attention. First, we have found three-fold variation across the country in the use of imaging per Medicare beneficiary. This is twice as much variation as we find for major procedures. In addition, researchers at Dartmouth have found that high use of imaging does not necessarily correlate with better outcomes, nor does high use of imaging correspond with lower cost for other services.

Let me be clear here. For individual imaging services, the improved outcomes can be demonstrable, easily seen, or the substitution for other services is readily seen. Research shows, however, that more in the aggregate is not necessarily better.

We have also found that other researchers, as well as private purchasers of imaging, have found evidence of quality problems, including problems with improperly maintained equipment or poor image quality. In addition, there are some problems with interpretation of results.

It is difficult to gauge how prevalent these problems might be based on a limited number of studies with small sample sizes. MedPAC's concern, however, is that whatever problems exist are likely to increase as imaging rapidly moves to office settings from institutional settings where there is more oversight, both by outside agencies and by peers. This risk is particularly great given the increasing sophistication of both the equipment and the techniques. It is important to keep in mind that while good imaging can improve outcomes, if imaging is not done well there is great risk in that for the patient as well.

So what does MedPAC recommend? With regard to quality, we recommend that Congress direct HHS to set standards for all providers who bill Medicare for performing and interpreting diagnostic images. This is an approach that has been successfully applied to mammography services. With regard to the growing volume and intensity of service, we recommend that CMS develop tools that measure resource use by physicians--all services, not just imaging--and provide confidential feedback to physicians on how their pattern compares with their peers.

Second, we recommend that CMS expand the coding supplied to Medicare claims to help counteract unbundling and other billing problems.

Third, we recommend that CMS work to improve the accuracy of the rates paid for imaging services.

Finally, we recommend that CMS strengthen rules that limit physician financial incentives to order more imaging services. I am pleased to say that CMS has, in fact, taken at least some steps on each of these recommendations related to volume and intensity.

Taken together, MedPAC believes that these recommendations about quality and cost will help increase the value received for the money spent on imaging services, both by the program and by Medicare beneficiaries.

Thank you. I look forward to your questions.

[The prepared statement of Glenn M. Hackbarth follows:]

PREPARED STATEMENT OF GLENN M. HACKBARTH, CHAIRMAN, MEDICARE PAYMENT ADVISORY COMMISSION

Chairman Deal, Ranking Member Brown, distinguished Subcommittee members, I am Glenn Hackbarth, Chairman of the Medicare Payment Advisory Commission (MedPAC). I appreciate the opportunity to be here with you this morning to discuss the quality and volume of imaging services for Medicare beneficiaries.

Technological progress in imaging over the past years, and its promise for improving diagnosis, treatments, and health outcomes are impressive. In addition, improvements in technology have made those services available outside the hospital in settings such as imaging centers and doctors' offices—with concomitant improvements in convenience for patients. However, at the same time there has been rapid and sustained growth in the volume of imaging services for Medicare beneficiaries; and there are concerns about potential overuse of imaging services, quality problems, and possible

inaccuracies in Medicare payment rates. As an example of the rapid growth in imaging, according to the Wall Street Journal, there are now more magnetic resonance imaging (MRI) scanners in the Pittsburgh area than in all of Canada and, in 2003, there were over 13 computed tomography (CT) scans provided for every 100 members of the largest health plan in the area.

The Commission has investigated imaging quality and growth through data analysis, consultations with private sector experts in the management of imaging services, discussions with medical specialty societies, and a review of the available literature. After public discussion and deliberation the Commission, by a unanimous vote among those present, recommended in our March 2005 report that:

- the Secretary of HHS improve Medicare's coding edits for imaging studies,
- the Congress direct the Secretary to set standards for all providers who bill Medicare for performing and interpreting diagnostic imaging services,
- the Secretary measure physicians' use of imaging services so that physicians can compare their practice patterns with those of their peers, and
- the Secretary strengthen the rules that limit physicians' financial incentives to order more imaging services.

Taken together, these actions should help add value to the imaging services Medicare buys.

While we are pleased that some of our recommendations have been adopted by the Congress and the Centers for Medicare & Medicaid Services (CMS), we believe that it is important for all of our recommendations to be implemented. The concerns identified in our March 2005 report have not diminished.

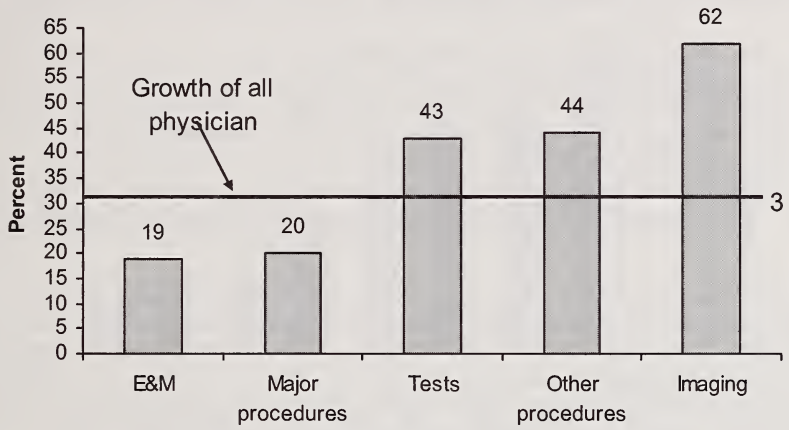
Growth has been dramatic

Diagnostic imaging services paid under Medicare's physician fee schedule grew more rapidly than any other type of physician service between 1999 and 2004. While the sum of all physician services grew 31 percent between those years, imaging services grew twice as fast, by 62 percent (Figure 1). This measure is the growth in the volume and intensity of services per beneficiary; we have removed changes resulting from increases in the number of beneficiaries and changes in prices during those years. Not all imaging services grew at this rate; some grew more slowly while some grew faster. Advanced imaging and nuclear medicine services, which are among the most expensive studies, led the way: MRI of parts of the body other than the brain grew by 140 percent; nuclear medicine grew 112 percent; and CT of parts of the body other than the head also grew 112 percent (Figure 2).

In dollar terms, Medicare spending for imaging services paid under the physician fee schedule (including beneficiaries' cost sharing) grew by nearly 90 percent, from $5.8 billion in 1999 to $10.9 billion in 2004. Increased spending on these services has also led to higher Part B premiums for beneficiaries.

FIGURE 1

Imaging shows highest cumulative growth in services per beneficiary (1999–2004)

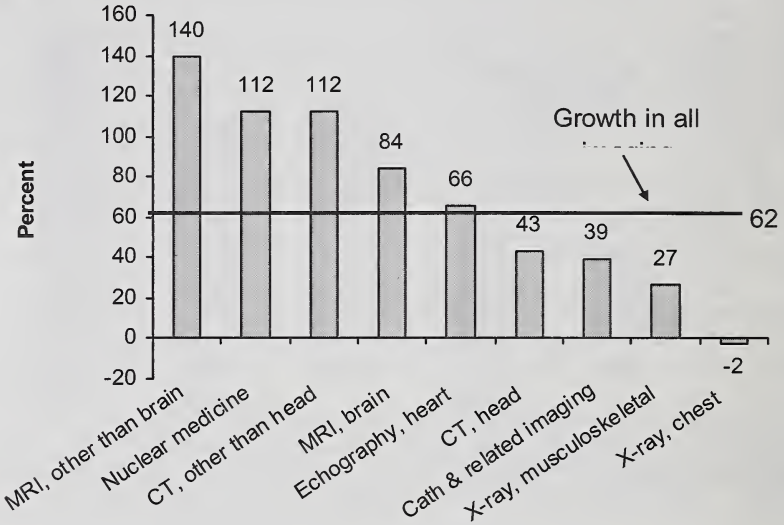


Note: E&M (evaluation and management).
Source: MedPAC analysis of Medicare claims data.

Some argue that much of this increase was attributable to the movement of imaging from hospital outpatient departments to settings paid under the physician fee schedule. However, we estimate that only about 20 percent of the growth in the volume and intensity of fee schedule imaging services between 1999 and 2002 was related to the migration of imaging from facility settings (such as hospitals) to physician offices. The remaining 80 percent of growth was related to factors other than shifts in site of care. The movement of imaging from outpatient departments to physician offices raises another concern: the institutional standards that govern the performance and interpretation of studies in hospitals are usually absent in physician offices.

FIGURE 2

Cumulative growth in imaging volume per beneficiary varies (1999□2004)



Note:MRI (magnetic resonance imaging), CT (computed tomography), cath (cardiac catheterization).
Source: MedPAC analysis of Medicare claims data.

The growth in imaging services could be driven by various factors, among them:

- technological innovation that has improved physicians' ability to diagnose disease and made it more feasible to provide imaging procedures in physician offices,
- patients' desire to receive diagnostic tests in more convenient settings,
- physicians practicing defensive medicine,
- possible misalignment of fee schedule payment rates and costs, and
- physicians' interest in supplementing their professional fees with revenues from ancillary services.

Some of these factors raise concerns that not all of the growth in the use of imaging services may be appropriate, and that quality safeguards may need to be put in place.

Are all imaging services appropriate?

The use of imaging services varies widely across the country. In fact, the average use of imaging services in one area can be three times the average use in another area. This variation is twice that seen in the use of major procedures. This finding raises a concern about the value of some of those services because geographic areas with a disproportionate use of health services in general do not have better health outcomes, according to researchers at Dartmouth Medical School (Fisher and Wennberg). Those researchers also find that wide variations in the use of discretionary services, such as imaging and diagnostic tests, are sensitive to the supply of physician and hospital resources.

In a separate study for MedPAC, Dartmouth researchers found that regions providing more imaging services do not have higher survival rates among Medicare beneficiaries. Their study examined whether long-term survival in three cohorts—

patients with heart attacks, colon cancer, and hip fractures—was better in regions with higher versus lower imaging use. They found that increased use of imaging services was not associated with improved survival in any of the three study groups. Although survival is a limited measure of quality, this analysis raises questions about the value of additional imaging.

In addition, there is specific evidence that at least some imaging services are overused. According to the American College of Radiology (ACR), patients with uncomplicated low back pain (without serious risk factors or signs of serious pathology) should not receive imaging studies. However, the National Committee for Quality Assurance found that nearly one-fourth of patients with low back pain in managed care plans received unnecessary imaging services, based on the ACR standard. These unnecessary tests included plain X-rays as well as costly MRI and CT scans.

Quality varies

According to published studies and health plans we consulted, providers vary in their ability to perform quality imaging procedures. In one study, published in *Radiology* (1998), BlueCross BlueShield of Massachusetts inspected 1,000 imaging providers to evaluate the quality of their equipment, technicians, and other features. These providers offered a variety of modalities, including MRI, CT, and nuclear medicine. Nearly one-third of the providers had at least one serious deficiency, such as film processing problems, failure to monitor radiation exposure, poor image quality, or uncalibrated equipment. Eleven percent of the providers had severe problems that could not be easily remedied, while 20 percent had deficiencies that could be remedied. Although chiropractic and podiatric offices were most likely to have had problems, many other specialties also had deficiencies.

According to a study in the *American Journal of Roentgenology* (2000), another health plan that inspected almost 100 nonradiologist offices that provided radiography services identified serious problems in 78 percent of the offices. These problems included lack of proper image identification (e.g., noting left or right side of body) and use of equipment that had not been inspected during the previous year.

In our March 2004 public meeting a panel of health plans and imaging benefit managers informed us that some providers fail to meet standards because their imaging equipment is old or not working properly. Physician offices sometimes acquire used equipment from a hospital and continue to use that equipment beyond its useful life.

Quality problems may lead to duplicative studies, inaccurate studies, missed or inaccurate diagnoses, and inappropriate treatment. A study published in the *Journal of Vascular Surgery* (2004) found that vascular ultrasound providers that were not accredited often produced inaccurate carotid ultrasound examinations. In that study, carotid ultrasound tests performed by nonaccredited labs for 174 patients were repeated by an accredited lab that followed standards for diagnostic criteria, testing protocols, and technician training. For 61 percent of the patients, findings by the accredited lab contradicted findings by the nonaccredited providers in a way that would affect patient management. The nonaccredited providers had either significantly overestimated or underestimated disease severity. Studies that overestimated severity could have led to unnecessary surgery for 88 patients and studies that underestimated severity could have resulted in no surgery for 19 patients who needed it.

There may also be problems with the quality of interpretation of imaging. For example, in one study published in the *Annals of Emergency Medicine* (1995), over 500 CT scans that were interpreted by emergency physicians were also read by radiologists. Radiologists disagreed with the emergency physicians' interpretations in 39 percent of the cases, some of which were potentially clinically significant misinterpretations (e.g., major false negatives or positives). Another study by an imaging benefit company found physicians' interpretation reports, which are an integral part of a diagnostic examination,

to be incomplete. The study found half of the reports examined lacked information on the indication for the study and many lacked information on the views taken.

Setting standards for imaging providers and interpreters

The lack of quality oversight for imaging tests provided in physician offices and rapid volume growth lead to our first recommendation: The Congress should direct the Secretary to set standards for providers who bill Medicare for performing and/or interpreting diagnostic imaging studies. To reduce the burden on CMS, the Secretary should select private sector organizations to administer the standards. As many physicians integrate imaging services into their office practices, ensuring that these studies are done by skilled technicians using appropriate equipment and interpreted by qualified physicians should improve the accuracy of diagnostic tests and reduce the need to repeat studies, thus enhancing quality of care and helping to control spending.

Requiring physicians to meet quality standards as a condition of payment for imaging services provided in their offices would represent a major change in Medicare's payment policy. Traditionally, Medicare has paid for all medically necessary services provided by physicians operating within the scope of practice for the state in which they are licensed. We believe that this policy change is warranted by the growth of imaging studies provided in physician offices and the lack of comprehensive standards for this setting. There are some limited precedents for this policy in imaging.

Current standards

Aside from a physician supervision requirement, no national Medicare standards for imaging apply to physician offices, and some imaging modalities, such as MRI, are not covered by any government standards. CMS has developed national standards for imaging provided in hospitals and independent diagnostic testing facilities. For example, hospitals that treat Medicare beneficiaries must comply with Medicare's conditions of participation, which include standards for radiology services. In addition, several Medicare carriers have minimum standards for the quality of some types of ultrasound studies performed in either hospitals or physician offices, but these standards have not been adopted nationally.

There are also two limited cases where Medicare has set standards for imaging interpretation. First, the Medicare carrier for New York (Empire) sets standards for physicians who wish to bill for interpreting an echocardiography study. Another exception is contained in CMS's recent decision to cover positron emission tomography (PET) scans for the diagnosis of patients with mild cognitive impairment and early dementia. The coverage decision specifies that tests be interpreted by physicians only in certain specialties, such as nuclear medicine and radiology, who have expertise in reading these scans.

There is a national standard for mammography. Under the Mammography Quality Standards Act, the Food and Drug Administration (FDA) develops and enforces quality assurance standards for mammography equipment, technical staff, and the physicians who interpret mammograms. The GAO has credited the FDA standards with improving the quality of mammograms without decreasing access. Failure rates for image quality decreased from 11 percent before the Act to 2 percent after.

State radiation control boards license facilities that use radiation-producing equipment (such as X-ray and CT machines), but their primary mission is to ensure patient safety rather than the quality of images, and the standards are not always comprehensive or rigorously enforced. The state boards do not regulate MRI or ultrasound services.

Several of the private insurers we interviewed require that hospital outpatient departments, freestanding facilities, and physician offices that provide imaging services meet basic standards. These standards relate to the imaging equipment, radiology

technicians, image quality, patient safety, and interpreting physicians. Plans and their vendors often require that providers become accredited by a private organization, such as the American Institute for Ultrasound in Medicine (AIUM), American College of Radiology (ACR), or the Intersocietal Accreditation Commission (IAC).

Developing standards

The Congress should grant the Secretary authority to develop standards. The Secretary should review the criteria used by private plans and accreditation organizations, and consult with accreditation organizations, physician groups, and manufacturers when developing these requirements. CMS should strongly consider setting standards for at least the following areas: the imaging equipment, qualifications of technicians, qualifications of the supervising and interpreting physicians, technical quality of the images produced, and procedures for ensuring patient safety.

Several private accreditation programs and one government agency have already developed standards for physicians who interpret certain types of imaging studies and prepare the reports. Accreditation organizations, such as the AIUM, ACR, and IAC, generally set minimum standards for some combination of professional training, experience, and education of physicians who interpret studies. The IAC has demonstrated that it is possible to forge agreement among different specialties on common standards. The IAC has convened representatives of several specialty groups to jointly develop facility and physician standards for echocardiography, nuclear medicine, and vascular ultrasound.

Although private plans sometimes base permission to bill for imaging procedures on the physician's specialty, the Commission has not recommended this approach. The practice of medicine is evolving quickly, and specialty training may change over time. Thus, CMS should develop criteria that allow physicians of different specialties to receive payment for interpreting studies. Similar to the requirements set by private accreditation organizations for interpreting physicians, Medicare's standards should be based on some combination of physician training, experience, and continuing education. Standards will vary for each major imaging modality.

To reduce CMS's administrative burden, the agency should authorize private accreditation organizations to verify that providers meet the quality standards set by the Secretary. CMS should also have the authority to change the roster of organizations that verify compliance. Private insurers often rely on accreditation programs to certify that their providers meet quality standards.

To allow CMS to implement national standards in all settings, the Congress should provide the Secretary with specific statutory authority to do so. Although CMS has set quality standards for various types of providers (such as hospitals and skilled nursing facilities), there are very few examples of federal standards that apply to physician offices (the primary exceptions are mammography and clinical laboratory tests, which are authorized by statute).

Measuring physicians' use of imaging services

The Commission also recommended: The Secretary should use Medicare claims data to measure physicians' resource use and confidentially provide information to physicians about their resource use relative to their peers. Educating physicians about their resource use should encourage those who practice significantly differently than their peers to reconsider their practice patterns. Measuring use of imaging services should be done as part of a broader initiative in which the use of a variety of types of services for episodes of care is measured. In our June 2006 report, we examined one method to achieve this—episode groupers. An episode grouper links all the care a beneficiary receives that is related to a particular spell of illness or episode and adjusts for patient characteristics. This tool could be used to provide information to physicians about their

practice patterns and could also help us examine whether imaging substitutes for other types of services.

Expanding coding edits

The Commission's third recommendation was: The Secretary should improve Medicare's coding edits that detect unbundled diagnostic imaging services and reduce the technical component payment for multiple imaging services performed on contiguous body parts. We are pleased that CMS and the Congress (as part of the Deficit Reduction Act, or DRA) adopted our recommendation to reduce payments for multiple imaging services performed on contiguous body parts in the same session.

A number of private plans adjust payments when providers bill for multiple imaging services performed on contiguous body parts. Some private insurers pay the full amount for the first service but a reduced amount (usually half) for the technical component of an additional study that is of the same modality (e.g., MRI or CT). This strategy is based on the premise that savings in clerical time, preparation, and supplies occur when multiple studies of the same modality are performed during one patient encounter. In last year's physician fee schedule final rule, CMS adopted this policy. The DRA required that savings from this policy go to the Medicare trust fund, rather than be redistributed among other physician services.

Currently, Medicare uses edits to determine whether a claim meets the program's payment rules. Some private insurers have developed their own set of coding edits that go beyond Medicare's existing edits. Some plans have implemented more rigorous policies to address unbundling of services—that is, separately billing for two procedures when one is a component of the other—and billing for mutually exclusive procedures. For example, one imaging benefit manager does not pay for both a CT of the head and CT of the maxillofacial region at the same time because the head includes the maxillofacial area. CMS should develop more extensive edits for imaging services.

Limiting financial incentives for physicians to order more imaging services

The Commission also recommended strengthening the rules that limit physicians' financial incentives to order imaging services for their patients. Specifically, we recommended that the Secretary should:

- include nuclear medicine and PET procedures as designated health services under the Ethics in Patient Referrals Act (the Stark law), and
- expand the definition of physician ownership in the Ethics in Patient Referrals Act to include interests in an entity that derives a substantial proportion of its revenue from a provider of designated health services.

These changes should reduce physicians' financial incentives to refer patients for additional imaging services, which should help control Medicare spending on imaging.

Physician ownership of health care facilities may create a financial incentive to order additional services. Studies by the GAO and others have found that physicians who invest in diagnostic imaging centers or who have imaging equipment in their offices refer their patients more frequently for MRI, CT, nuclear medicine, and ultrasound studies.
The Ethics in Patient Referrals Act prohibits physicians from referring Medicare or Medicaid patients for certain services to providers with which the physician has a financial relationship. It also prohibits those entities from submitting claims for services provided to patients referred by the physician-investor. The law applies to a set of "designated health services" (DHS), which includes radiology and certain other imaging services (MRI, CT, and ultrasound).

Until recently, CMS had excluded nuclear medicine from the Stark law's prohibitions. This decision allowed physicians to invest in freestanding centers that provide nuclear medicine procedures and refer Medicare or Medicaid patients to these facilities. The Commission recommended that CMS add nuclear medicine to the list of

designated health services because of the recent rapid growth of these services and their similarity to other imaging services. In last year's physician fee schedule final rule, CMS adopted our recommendation, effective in 2007. Prohibiting physicians from referring Medicare or Medicaid patients to nuclear medicine facilities they own should reduce their financial incentives to refer patients for these services.

In a final rule issued in 2001, CMS created a narrow exception that is inconsistent with the underlying intent of the Stark law. This exception permits physicians to own entities that provide services and equipment to imaging centers and other DHS providers, as long as the physicians do not own the actual entity submitting claims to Medicare or Medicaid. For example, physicians can buy an MRI machine from a manufacturer, lease it to an imaging center, and be reimbursed a fixed amount per use. This arrangement creates a financial incentive for the physicians who lease the MRI to the center to refer patients to that center, which could lead to higher use of services. Prohibiting these arrangements should help ensure that referrals are based on clinical, rather than financial, considerations.

Assuring the accuracy of imaging payment rates

We are also concerned about the accuracy of Medicare's payment rates for imaging studies. In a recent proposed rule, CMS proposed basing payments for the technical component of imaging services on resource use (these rates are currently based primarily on historical charges). These resources include clinical staff, medical equipment, and supplies. Equipment is a large share of the cost of many imaging services, such as MRI and CT. CMS's estimate of the cost of imaging equipment per use may be too high. The agency assumes that imaging machines (and all other types of equipment) are used 50 percent of the time a practice is open for business. We surveyed imaging providers in six markets and found they were using MRI and CT machines much more frequently, which should lead to lower costs per use. In addition, CMS assumes that providers pay an interest rate of 11 percent per year when purchasing equipment, but more recent data suggest that a lower interest rate may be more appropriate (a lower interest rate would reduce the estimated cost of equipment). CMS should revisit the assumptions it uses to price imaging equipment.

Impacts

Setting standards should increase the quality of imaging services provided to Medicare beneficiaries, not decrease access, and potentially decrease spending by reducing duplication of tests and unnecessary services. Physician resource measurement should educate physicians who have higher use, and has the potential to decrease spending in the long run. Improved coding edits should reduce inappropriate billing and thus decrease spending. Limiting financial incentives for physicians to order imaging services should also help control spending. Beneficiaries will not only experience higher quality imaging services if these recommendations are implemented, but will also benefit from reduced cost sharing and part B premiums.

MR. DEAL. Thank you. I will start it off.

Mr. Kuhn, I believe you testified that imaging services, such as CAT scans and MRIs, grew by 82 percent between 2003 and 2005, and that the equipment used to perform these services is routinely and quite frequently used in the physician office setting. Is that correct?

MR. KUHN. That is correct.

MR. DEAL. Okay. You also testified that the technical component of payment for some services performed in a physician's office, such as an

MRI of the brain or abdomen, are currently being reimbursed at 78 percent more than a hospital for rendering the same service.

Some providers would argue that the physician should be paid higher for the cost of this equipment, because hospitals can spread out the capital cost of the equipment, whereas the physician cannot. However, I am interested in your testimony regarding the equipment assumptions indicated by MedPAC. Specifically, you testified that if a machine is actually used most of the time, its cost is spread across the units of service, resulting in a lower cost per service. Therefore, since you stated that MRIs and other advanced imaging services grew by 82 percent in 2 years, isn't it logical to consider that perhaps the cost of the equipment that is highly utilized in the physician's office is, in fact, spread out over the cost of services that are provided?

MR. KUHN. That is correct, Congressman. There is a real marginal cost issue here that I think people need to think about, and the other issue I think this really brings forward in your question is an assumption that we make, and this is an assumption that goes back to 1997. We make an assumption in terms of pricing in the physician office that is going to be used 50 percent of the time, but I think over the last decade, what we have begun to see, at least MedPAC has evidence that they shared with us, information we are starting to get from independent diagnostic testing facilities and physician's offices that they are using the equipment more and more than 50 percent of the time.

And so basically what you see is that the more you use it, the less it is going to cost to use this equipment. So some people are saying well, you have got an apples and oranges comparison between the hospital outpatient department and the physician fee schedule that is out there, but if we were to update and move forward, I think, in terms of this utilization rate, I think you would see those numbers much more closely aligned than I think they currently are now.

MR. DEAL. There are two components; the payment for the professional component and the technical component that is being paid separately. Now as I understand it, you have testified that 78 percent higher rate in some cases for things like MRI are being paid to physicians in their offices versus the hospital outpatient setting. But you also point out, I believe, that the physicians receive an additional fee for reading those images. Is that correct?

MR. KUHN. Right. There are two parts to the physician payment, as you indicated, the professional component and the technical component. The DRA provisions only deal with the technical component, that is, the equipment, the staff, the information--the education, the material really to do the equipment component of this. The professional component, it is no different between the hospital outpatient and in the physician office.

So that is untouched by this particular provision. It is just the technical part where they are trying to make sure that we have a site neutral payment system.

MR. DEAL. Mr. Hackbarth, with regard to the private insurance sector, are they seeing the same type of percentages of growth in imaging in the private insurance area as we are seeing in the Medicare program and if so, what are they doing to try to curb their costs?

MR. HACKBARTH. They are seeing high rates of increase in imaging in the private sector. Some of our recommendations are similar to things being done by private payers, for example, coding edits is a widely used tool. Many private payers are also engaged in efforts to develop information for physicians in how their use of various resources, including imaging, compares to their peers. Some private payers go further than that to actually credential the physicians who do imaging and limit it to people. They will only pay for physicians who have certain training. Some insurers also require prior authorization for expensive imaging procedures.

We did not embrace those particular steps. We limited our recommendations to things like the coding edits, getting the prices right, and providing feedback to physicians. We did that in recognition of the complexity of this issue and how challenging it is to identify and encourage the appropriate imaging while discouraging the inappropriate. It is a tough task.

MR. DEAL. Thank you.

Mr. Pallone, you are recognized for questions.

MR. PALLONE. Thank you, Mr. Chairman. I wanted to ask my questions of Mr. Hackbarth.

The witnesses on the second panel are going to focus a great deal on provider reimbursement and also on standards for imaging, but what today's testimony does not sufficiently focus on, in my opinion, is the effect on the beneficiary of both the growth in imaging services and the changes in Medicare's payments for these services. To the extent Medicare is overpaying for services, the beneficiary too winds up overpaying because their co-sharing is based on Medicare's payment rates, and to the extent services are growing inappropriately, the beneficiaries' Medicare Part B premiums are increasing as a result.

So I just wanted you to comment on the effect of all this on beneficiaries and their out-of-pocket expenses.

MR. HACKBARTH. Yes. Well, you have well-summarized the impact. It is both at the point of service, in terms of patient cost sharing, and in terms of the rapidly increasing Part B premium. Herb, in his statement, indicated the rapid growth in the Part B premium, and a big

piece of that growth in Part B expenditure is, in fact, attributable to imaging.

MR. PALLONE. I don't know if you wanted to comment, too, Mr. Kuhn?

MR. KUHN. Yes, Mr. Pallone. It is a good point and I agree with Glenn. I think you summarized it very well. What we are seeing here is kind of two parts. In addition to the beneficiary, there is the co-payment, and so if there is a higher fee in the physician office, the co-payment is going to be higher as a result of that. But also, this is a real driver in terms of the Part B premium. As indicated last week in the mid-session review, we came out with the latest estimates of what we think the Part B premium will be in 2007, and it looks like it is going to be about $98.40. That is about an 11 percent increase from the current rate of about $88.50. There are a lot of drivers in that, but the largest drivers are hospital outpatient services and physician services. And within the physician services, medical imaging is really a major driver as well.

MR. PALLONE. Thank you.

I want to go back to Mr. Hackbarth again. MedPAC has recommended that the Secretary of HHS establish quality and training standards for providers who bill Medicare for imaging services, and Medicare has not previously required physicians to meet quality standards as a condition of payment for imaging services. Do you feel that imaging services uniquely require such standards, and aren't there already Medicare standards for imaging services provided in an outpatient hospital facility, and what are other payers doing in this area?

MR. HACKBARTH. Right. As a general proposition, Medicare does not establish quality standards service-by-service, so in that sense this would be breaking new ground. But there are some precedents. I mentioned, I think, earlier the mammography quality standards which, in fact, have been shown to improve the quality of mammography imaging in work done by GAO. So that is a recent precedent for this. There are also some more narrow precedents where in its coverage decision on PET scanning, for example, CMS included some standards related to qualifications, and some of the individual carriers also have quality standards for particular procedures.

It is an important step and we think it is one that is warranted because of the rapid growth, and as I said earlier, the migration of this complex and very important activity from institutional settings to physician offices where there is less oversight.

MR. PALLONE. Okay. You might get the impression that MedPAC is advocating that only radiologists should perform imaging, but I know that doesn't reflect your recommendations as I understand them. Isn't MedPAC simply saying that physicians who are paid by Medicare for

imaging services, regardless of whether they are radiologists, cardiologists, gynecologists, or others, be trained and meet certain standards? Isn't that right?

MR. HACKBARTH. Absolutely, and there has been considerable misunderstanding on this point, so I appreciate your clarifying it.

We are not recommending that only radiologists be permitted to do imaging for Medicare beneficiaries. We are saying that all physicians who do, as well as the staff who do the technical component, ought to meet quality standards that have to do with their education, training, and experience.

MR. PALLONE. Okay. Do you recommend that the Secretary of HHS should select private-sector organizations to administer any new standards for imaging providers and interpreters, and what specific private-sector organizations would you recommend and why?

MR. HACKBARTH. Well, we do recommend that the actual review of provider qualifications be done by private organizations. I want to emphasize, though, that we think the standards ought to be set by the Department and then the administration of those standards be done by private organizations. We recommend that in part to try to minimize the workload on CMS, and in part, because there are existing organizations who do this sort of work, among other things, for private payers. And so we think that the sort of people who can do the work well are available and we ought to use those resources.

MR. PALLONE. All right, thank you.

Thank you, Mr. Chairman.

MR. DEAL. Thank you.

Dr. Norwood is recognized for questions.

MR. NORWOOD. Thank you, Mr. Chairman.

Mr. Kuhn, I have about five questions for you. I will submit them in writing. Can you answer those in 2 weeks?

MR. KUHN. We will answer you in 2 weeks, Dr. Norwood.

MR. NORWOOD. That is very acceptable. We need to move this quickly and we don't have months and months. CMS, for example, takes months and months, but I presume you won't.

MR. KUHN. We will do it in 2 weeks.

MR. NORWOOD. That is wonderful.

MR. KUHN. Do you yield back your time?

MR. NORWOOD. No, I don't.

One question for you, however. How much of the growth in imaging utilization is a result today of increasing the amount of women receiving mammograms? How much does that contribute to the increase?

MR. KUHN. I don't know if I have the specific breakdown in terms of mammography and how much that has led to the increase here. It is

obviously a very valuable service, as we heard earlier, because it saves lives.

MR. NORWOOD. Does anybody have that number?

MR. KUHN. I don't know if we have that number, but one thing I would just say on the mammography is we know we have been talking about this provision in the DRA. It is outside of this provision in the DRA because under current law, there is a site neutral payment for mammography, so it is the same in the physician office as it is in the outpatient.

MR. NORWOOD. But we don't know the answer to the question?

MR. KUHN. I don't know the answer, but we can find out.

MR. NORWOOD. How much of the growth is a result of MRI or CT scans used to identify the nature and location of strokes? What percent of that increase growth is caused by that?

MR. KUHN. I don't know if we have the coding edits that can show that, but in those two particular areas--we group imaging into four different areas and that is in a category of advanced imaging, and that is probably the single largest growth area we are seeing in terms of measuring it right now.

MR. NORWOOD. So what percentage is it?

MR. KUHN. I could look at the chart here real quick--

MR. NORWOOD. I don't--does anybody know the answer? And if you don't, just say I don't know.

MR. KUHN. I don't know right now, but we could find out. I think it is--advanced imaging, it looks like the growth rate was 25 percent in 2005.

MR. NORWOOD. It seems to me that it is pretty important that you understand totally and completely what these increases are all about.

Mr. Hackbarth, I have eight questions for you in writing.

MR. NORWOOD. Can I get an answer in 2 weeks?

MR. HACKBARTH. Sure.

MR. NORWOOD. That is very kind of you, sir. Thank you.

I made some notes. Let me see if I can read them.

You said increased imaging for--doctors are increasing what they do in imaging to supplement their professional fees. You did say that?

MR. HACKBARTH. Yes.

MR. NORWOOD. Can you--

MR. HACKBARTH. Some physicians.

MR. NORWOOD. Can you prove that to me?

MR. HACKBARTH. I certainly can, among other things, give you examples of presentations that are made at physician conferences that are pitched at exactly that.

MR. NORWOOD. So you can prove it? It is pretty important because you are saying to us this is one of the major causes, and we have legislation that cuts the heck out of what we pay for these fees, and if that is true, it needs to have absolute proof to it.

MR. HACKBARTH. Dr. Norwood, I want to be clear that I am not saying that that is true of all physicians.

MR. NORWOOD. I understood that part.

MR. HACKBARTH. There are some physicians and--

MR. NORWOOD. I speculate you are right. I want proof.

MR. HACKBARTH. Well, I can give you examples of it happening.

MR. NORWOOD. Okay, then you need to give me examples of it not happening so I understand are we talking about .001, are we talking about a normal occurrence? I mean, we have cut what we pay for imaging which is absolutely vital to healthcare today, and the patient is the one maybe in the end who is not going to fare well under this, and you say you have a study--and you and I both have been in this town long enough to know, you make a study say anything you want it to say. I want to be sure we are right about this as we move forward.

You also used the word "high use of imaging does not produce increased good outcomes." First, what does high use mean, and can you prove that statement?

MR. HACKBARTH. Well, what I said was that individual cases of increased imaging can, in fact, improve outcomes. I think we both know those examples.

MR. NORWOOD. You said that.

MR. HACKBARTH. The research indicates that higher use of imaging services in the aggregate--

MR. NORWOOD. Yes, I understand.

MR. HACKBARTH. --in total does not correlate with better outcomes.

MR. NORWOOD. I am trying to figure out who determines what high use is. I think I have had so many CAT scans I can't believe it, but I am sure happy to be alive. Now, was one of them not needed? I don't know. Who measures that?

MR. HACKBARTH. Well, on that particular issue, we are not saying that high use is a particular number. You just look at the change in volume of the imaging and then correlate that with improved outcomes.

MR. NORWOOD. Lastly, Congress cannot set standards. You said Congress should. Congress can't anymore than CMS can set standards. I would rather have Congress do it. We have got more practicing physicians in Congress than we have got bureaucrat physicians in CMS. So in this case, I would rather Congress do it than CMS, but literally, neither one can actually do it.

I see my time is up, Mr. Chairman.

MR. DEAL. I thank the gentleman.

Ms. Capps.

MS. CAPPS. Thank you to our witnesses and I would like to ask questions of each of you, so I hope for brief answers.

Dr. Kuhn--Mr. Kuhn, I am concerned about how the cuts enacted in the Deficit Reduction Act could affect cancer patients' access to needed services. Radiation therapy is less invasive, less expensive, and more curative than some other cancer treatments, and it has been brought to my attention by the American Society for Therapeutic Radiology and Oncology that due to a lack of discussion before inserting these cuts into the DRA, it is really unclear whether radiation therapy is included. Mr. Chairman, with your permission and unanimous consent, I would like to have the statement of the American Society for Therapeutic Radiology and Oncology inserted into the record, which explains their views on this. I wanted to ask you a yes or no question--

MR. DEAL. Without objection.

[The information follows:]

ASTRO
American Society for Therapeutic Radiology and Oncology

Statement For the Record of the

American Society for Therapeutic Radiology and Oncology (ASTRO)

to the

Subcommittee on Health

House Energy and Commerce Committee

"Use of Imaging Services: Providing Appropriate Care for Medicare Beneficiaries"

July 18, 2006

On behalf of the American Society of Therapeutic Radiology and Oncology (ASTRO), we appreciate this opportunity to submit written testimony to the House Energy and Commerce Subcommittee on Health on the "Use of Imaging Services: Providing Appropriate Care for Medicare Beneficiaries." ASTRO is concerned that if the imaging caps contained in the Deficit Reduction Act (DRA) are applied to radiation therapy delivery and management services, it could significantly limit the treatment options for cancer patients.

ASTRO is the largest radiation oncology society in the world, with more than 8,500 members who specialize in treating patients with radiation therapies. Representing radiation oncology, biology and physics, the Society is dedicated to the advancement of the practice of radiation oncology by promoting excellence in patient care, providing opportunities for educational and professional development, promoting research and disseminating research results and representing radiation oncology in a rapidly evolving healthcare environment.

Cancer is the leading cause of death in the United States and a primary health concern for many Americans. One in three people will develop cancer in their lifetime. This year, almost 1.4 million Americans will be diagnosed with cancer. More than 564,000 patients die of this disease each year. In recent years, Congress has expanded Medicare coverage for a number of cancer screening services. ASTRO strongly supports these coverage expansions. As you know, early detection of cancer can significantly increase survival. It is counterintuitive for Congress through these DRA provisions to act to reduce access to critical tools used in the diagnosis of cancer. Decreased access and increased wait times for services will negatively impact cancer survival.

Nearly two-thirds of all cancer patients will receive radiation therapy during their illness. In light of these realities, curing patients of cancer requires a constant commitment to advancing treatment paradigms at all levels in the healthcare system. To ensure excellence in patient treatment and improved outcomes, we must invest in the latest technology available. The

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practice of radiation oncology depends heavily upon these state-of-the-art technologies as we seek to offer our patients an improved opportunity for cure or palliative care.

Radiation oncologists are an integral part of the multidisciplinary management team for the cancer patient, collaborating closely with physicians in related disciplines in the overall management of patient care. Radiation therapy is the most successful and minimally invasive form of cancer treatment. New and innovative ways to improve the treatment of patients with cancer and benign diseases with radiation are constantly being sought. As the practice continues to advance technologically, the use of medical imaging devices has become an integral component of radiation oncology cancer management. Linking imaging with treatment in real time provides a significant opportunity to improve the efficacy of radiation therapy and improve outcomes for cancer patients. (Please see the attached example illustrating the use of medical imaging and radiation therapy for a Medicare beneficiary with prostate cancer.)

The use of medical imaging in radiation oncology significantly benefits millions of cancer patients. Radiation therapy is typically delivered over a series of weeks. The use of imaging permits the radiation oncologist to precisely target the treatment to a localized area. In many cases, this precision means avoiding unneeded surgery or hospitalization. The use of imaging technology in radiation oncology not only improves precision and tumor control, but can also save money by reducing or eliminating nonessential or inappropriate treatment. For example, PET scans can eliminate many futile surgeries for lung cancer patients.

Over the past decade, improvements in medical imaging modalities, such as CT, ultrasound, MRI and PET, have been incorporated into the management of radiation oncology patients. This has led to the development of a new treatment paradigm called "image-guided radiotherapy" or IGRT. IGRT is radiotherapy that uses images of the patient's internal anatomy to better target the radiation dose to the tumor while reducing radiation exposure to healthy tissues. Image guidance leads to improved control of the tumor while simultaneously reducing the potential for side effects due to radiation of healthy tissue surrounding the tumor. Studies show that by combining an X-ray volume imaging system with radiation therapy equipment to provide "real time" images of the tumor during treatment, the accuracy of the radiation can be significantly improved. These medical images are taken simultaneously as radiation therapy is delivered to a patient.

One of the major challenges in treating patients with lung tumors with radiation is precisely targeting a moving tumor while simultaneously decreasing the amount of healthy tissue that may be exposed to radiation. Another new technology in the area of image-guided guided radiotherapy is four-dimensional (time varying) computed tomography (4-CT). This new form of treatment will enable the radiation oncologist to take into account the phases of inhalation and exhalation to minimize damage to healthy lung tissue. This technology is promising because it will improve the ability to develop more precise treatment plans for the delivery of radiation therapy to lung cancer patients.

As you know, in the Deficit Reduction Act of 2005 (DRA) Congress capped the technical component for imaging services at the hospital outpatient department rates. This provision was

included in the final version of the DRA conference agreement, but the potential impact of this cut was never discussed in a public forum. It is our understanding that in its deliberations on the DRA, Congress did not consider whether these cuts would apply to radiotherapy. However, Congress did exempt mammography from the imaging provisions, indicating Congress' intent to support access to needed services for cancer patients. We appreciate the recognition of the important role imaging plays in identifying and treating cancer patients. ASTRO is concerned that if the DRA caps are applied to radiation therapy treatment, planning, and delivery services, treatment options for cancer patients could be limited.

ASTRO is a member of the Access to Medical Imaging Coalition. This is a broad coalition comprised of physicians and manufacturers advocating for a two-year delay of the DRA imaging cuts so that the Government Accountability Office can conduct a study to assess the impact these cuts will have on patient access to needed services. ASTRO supports the Access to Medical Imaging Act of 2006 (HR 5704) that was introduced with broad bipartisan support as well as the support of a number of members of this Subcommittee.

Medical imaging is an essential tool in the practice of radiation oncology. Patient safety and quality of care would be severely compromised without the use of imaging technology in the delivery of radiation therapy. Researchers stand on the brink of life-saving discoveries in the area of radiation therapy treatments which could be impeded by reimbursement cuts. The use of medical imaging in modern radiation therapy treatment continues to offer exciting possibilities with the potential to revolutionize the way we treat cancer.

Radiation therapy is less invasive, less expensive, and more curative than many other cancer treatments. The clinical outcome of radiation therapy is being vastly improved by the precision of tumor localization and dose delivery during treatment, and that improvement can be attributed to various techniques using imaging. It is vital that limitations to these important imaging services are not applied to the planning and treatment of cancer with radiation therapy. We look forward to working with Congress and CMS to assure that America's cancer patients continue to have access to needed services.

ASTRO
American Society for Therapeutic Radiology and Oncology

Clinical Example Illustrating the Use of Medical Imaging and Radiation Oncology

A 66-year-old-male presents with prostate cancer. The patient opts for external beam radiotherapy as his treatment of choice. The radiation oncologist elects to deliver a series of radiation doses to the patient's prostate and seminal vesicles using highly conformal radiotherapy to spare his rectum and bladder.

The patient has three gold markers placed in the prostate transrectally under ultrasound guidance. Subsequently, the patient undergoes CT simulation, positioned supine.

During treatment, the patient is first aligned with the in-room laser system. Two sets of digital x-rays are acquired to visualize internal anatomy and the implanted marker positions immediately prior to treatment. This is done using X-ray units recessed into the linear accelerator floor and ceiling-mounted detectors or using an X-ray unit attached to the gantry or X-rays with an electronic portal imaging device (EPID).

The X-ray images are compared with pre-treatment digitally reconstructed radiographs (DRR) in the same position. The radiation therapist then registers the reference position of the markers with the X-rays obtained immediately prior to the treatment.

A radiation oncologist, medical physicist, or trained therapist under the supervision of the radiation oncologist reviews the automated image fusion. The patient is then repositioned for treatment delivery using the patient setup adjustments calculated from the registration process. The adjustments are performed by applying the offsets to the treatment couch. The position of the treatment couch is verified by infrared markers attached to the treatment couch and detected by special cameras mounted in the room. Highly conformal radiotherapy delivery is then administered.

Patient outcome
After a series of image guided radiation therapy treatments, the patient's prostate cancer is cured with few side effects. He avoids the need for a radical prostatectomy and the associated negative effects (*e.g.*, incontinence and sex dysfunction). The patient's bladder and rectum are not affected by the radiation, so the patient's function remains normal (*e.g.*, no increase in the frequency of urination and no increase in the frequency of bowel movements).

MS. CAPPS. --whether radiation therapy is included in these cuts?

MR. KUHN. My understanding is yes.

MS. CAPPS. So the question then is, very brief answer, how do we maintain access to these services for cancer patients?

MR. KUHN. I think that is going to be the real key thing when we put out the proposed reg, which we should have out in the next few weeks. We are going to have a nice discussion about this with the stakeholder community at large when they can comment about the provisions that we put forward, based on our understanding and our read of the law, and have a dialogue on that.

The issue here, however, is what Congress was trying to do, as I understand with this provision, is really try to create a site neutral payment system, that we had a major delta between payments in an outpatient setting and a physician office setting, and was that appropriate not only for payments for the Medicare program, but was also that appropriate for the Medicare beneficiaries as well.

And so, we have got a couple of objectives here, to make sure that we can have fair and appropriate payment, treat the beneficiaries appropriately and fairly, but also make sure, as you indicated, that we keep this important access available to everyone.

MS. CAPPS. Well, thank you. We will be watching very carefully because it isn't set and it is very critical how the path goes on in the future.

Mr. Hackbarth, I think you made some excellent points about the need to set and enforce better quality standards for physicians who perform and interpret diagnostic imaging services, while also more closely evaluating the use of imaging services by physicians to rid out possible overuse. Physicians will need to be empowered to be able to do this or even fraud within the system, we give them opportunities and ways to do it. If I understand you correctly, these efforts--these kinds of efforts should help reduce spending on these services. Is this true, in a brief answer, so I can give you a chance to follow up?

MR. HACKBARTH. I think what you are referring to is our proposal to feedback to physicians--

MS. CAPPS. Right.

MR. HACKBARTH. --information about not just their use of imaging, but their overall patterns of care--

MS. CAPPS. Right.

MR. HACKBARTH. --and do so initially in a confidential manner so physicians can compare themselves to peers. We think that is a very important approach for helping physicians improve their practice.

MS. CAPPS. And I would like to request of my colleagues that we find a way to use that information and be a part of that oversight. I think self-police and self-enforcement can go a long way, although it isn't the bottom line. But I don't think we are taking advantage of that expertise, which surely wants to save cost as well.

But here is the follow-up. However, so far the only congressionally enacted proposal involves cutting just across the board all outpatient imaging, even though we know that the procedures save lives. It is like we know there is waste and abuse out there, but we are going to cut it all, even though we don't know, with a sledgehammer.

But let me give you the example, and then you can comment. A Mayo Clinic report which concluded that increased use of ultrasound guided fine-needle aspiration used to diagnose thyroid cancer has reduced the number of unnecessary surgeries and improved costs. Shouldn't we wait to see the results of these kinds of studies and efforts before we do this blanket cut to reimbursement? Wouldn't it be risky and really appalling to jeopardize patient access to imaging services without waiting to see if we can't use other methods to reduce cost savings?

MR. HACKBARTH. MedPAC has not specifically looked at the DRA provision on limiting payment for imaging services, and I want to emphasize that because some people seem to think that it originated with MedPAC. It did not.

MS. CAPPS. Well, who can do it? How should it be done?

MR. HACKBARTH. Well, what MedPAC has done is we have looked at the general idea of trying to set payment rates at the level of efficient providers. Ideally, you would not have different payment rates solely based on the site of service and pay more for a less efficient provider of the same service.

MS. CAPPS. Right.

MR. HACKBARTH. So we want to set it at the level of efficient providers. Now, operationalizing that for imaging services or any other particular service is a fairly complicated task. You have got to make adjustments for the different types of payments--patients, rather, treated in different settings. You have got to be sure you have got the cost of efficient providers accurately calculated.

So in concept we can understand where the DRA provision is coming from, but we have not looked at the specifics of it, and I don't have any position on it.

MS. CAPPS. I know I have used my time, but just a yes or no. Is anybody doing this, to your knowledge?

MR. HACKBARTH. Well, I assume CMS is.

MR. KUHN. Obviously, we are looking at this very hard in terms of the provisions we have already put forward in terms of the contiguous body part changes we made, and obviously we will move forward in terms of the implementation of the DRA provision as well.

MS. CAPPS. I think there is a big gap here.

Thank you very much.

MR. DEAL. The gentlelady's time has expired.

I am recognizing members on the basis of order of appearance and seniority, and in that regard, Mr. Shimkus is recognized next for questions.

MR. SHIMKUS. Thank you, Mr. Chairman. Welcome to the panelists, and Herb, it is good to see you again. We have fought a lot of fights together.

As both you know, I was involved in part of the Deficit Reduction Act, was working with Gene Green of Texas on the abdominal aortic aneurysm provisions, which we were very excited about having that in the process, of course. That is what happens when you have big legislation. For every good thing that gets in, then there are other issues that don't, and then you have to cast the tough vote, and sometimes you may not be fully aware of all the other provisions.

Having said that, there is a question about the cuts and in essence, the non-invasive diagnostic vascular studies. They really contain no imaging, so there is a question out there in the community, will they be affected by these cuts, and I want to submit a more precise question, because I am not smart enough to say it right without sounding terrible, but to make sure I get it right. But if you understand my question, I would welcome an answer on what does it deal with if it is a vascular study that contains no imaging? Is it part of these perceived reductions?

MR. KUHN. No, I think your point is well taken, and we have had a number of organizations that have come in to see us since the DRA was passed to have discussions about this kind of issue about whether the provisions in the DRA just deals with diagnostic imaging, or does it deal with therapeutic imaging? So there is a lot of different breaks here that we are spending a lot of time with our general counsel as we evaluate the DRA, and quite frankly, Mr. Shimkus, at this time I don't think I have an answer for you, but we should when we have our proposed rule come out again, hopefully in the next 3 to 4 weeks, where we will have a chance to share with everybody our interpretation of what the statute says and then let the community at large give us comments on that.

MR. SHIMKUS. Would it be helpful for me to submit this question formally, or is it just as well we wait to read your ruling?

MR. KUHN. I think it would be helpful to have it in the record, so if you want to go ahead and submit it, we will make sure that we get it answered that way, and then we will also have it as part of the rule as well.

MR. SHIMKUS. Great, thanks.

The other question I have on this whole debate, which I thought would have been asked before I had a chance to ask questions, last week we had a hearing on medical liability, and other than just the tort issue,

but what other options are out there. So as far as this, one of the questions would be is a lot of this, how it is termed additional utilization, has there been any look to see what part of this is defensive medicine that maybe the utilization is just to protect the providers of the healthcare services?

MR. KUHN. You know, it certainly is an issue, and maybe Glenn can speak to this as well, because they have looked at this and other issues pretty hard.

Beginning last year when we do an annual letter to MedPAC in the spring where we talk about the SGR issue and kind of give an indication of what it is going to look like for the following year, last year, and again this year, we went through a great deal of detail to provide a lot of specificity of what was out there, and that was when we really began breaking down into the level of detail that we did on imaging. One of the questions that we have asked the provider community overall is what is driving this in imaging and all these other areas we are seeing tremendous growth and physician spending, but particularly in imaging we really wanted to know what were all the factors that have been talked about here, but in particular, defensive medicine. We are getting a lot of mixed reports, but I think the general consensus we hear from the provider community is yes, that is one factor that is part of it.

I will see if Glenn has any thoughts on that as well.

MR. HACKBARTH. Yeah, I think unquestionably that is a factor in the increase. Off the top of my head, I couldn't try to quantify what percentage of the increases are due to fear of malpractice.

MR. SHIMKUS. If I may butt in, I think based upon my friend, Dr. Norwood, I think what would help us is to get some quantifiable numbers in which we can really point--I know it is difficult to do, but I think that would be helpful to us.

But let me do the flip side of the coin. I have 33 seconds left.

What about any data that shows improved patient outcomes, based upon all this additional screening? I mean, on the, obviously, on the defensive medicine, but what about even though it may be perceived as over-utilization, is there an improvement in patient outcome?

MR. KUHN. No question, I am sure there are improved patient outcomes, and there have got to be a lot of studies that we could all produce to show that, which is good. I mean, the fact that you don't have to do an incision to explore something, the fact that something that is hidden from view can be seen with imaging I think is just wonderful. And I think what this raises is the cost benefit of technology. It is a net benefit to society as we go forward, but I think the second part that anybody does to benefit society in terms of technology also has to look at

is that there also has to be equal incentives to make sure that we have quality and not wasteful spending in this area as well.

And so those have to be balanced as we go forward here.

MR. SHIMKUS. Mr. Chairman--unless you want to answer, my time is expired.

MR. DEAL. I thank the gentleman.

Ms. Eshoo is recognized for questions.

MS. ESHOO. Thank you, Mr. Chairman, and I apologize for not being here from the beginning. I had an Intelligence Committee meeting that I tried to divvy up the time. This is an important hearing, and I think it is important to summarize how we arrived here.

Deficit Reduction Act was voted on in the House. These cuts were not in that bill. There was a conference committee. Certainly, the Chairman of the full committee, Mr. Barton, the Chairman of our subcommittee, Mr. Deal, were conferees. It is my understanding that Mr. Dingell and Mr. Brown were not included in the ultimate process where the outcome was determined for these cuts to imaging. Our committee had many hearings and we have many members on both sides of the aisle who have worked to support the enhancement of imaging in our country. We all know the benefits of it. Our colleague who has undergone a long, rough road to be back in, I think, full health now just said a little earlier that he is most glad to be alive, and that imaging services were a part of that. So, you know, it is important to understand how this darn thing happened.

Now there are $2.8 billion in imaging cuts over five years, $8.1 billion over 10. Imaging represents about one-tenth of Medicare spending, and yet the cuts comprise roughly one-third of the total Medicare cuts in the bill. Now, CMS is here and I think that you have probably got your marching orders from these conferees.

What I would like to know from you, Mr. Kuhn, is have you examined any kind of savings that have come about from imaging services? It doesn't seem to me that it is prudent to be going at this with a meat axe, if, in fact, we all acknowledge how much a necessary part of the system imaging is and what it has produced for the American people. You know, on the one hand, Congress is celebrating it. On the other hand, they are saying cut the hell out of it. We have to be pragmatic about this. I don't know what the conferees were thinking when they went to this. Maybe our Chairman today wants to explain it, because I think he voted for it. It is not what the House voted for. I didn't vote for that bill, and it is not what the House voted for. This was jammed into the bill at the end of the process.

So have you done any kind of an analysis of what the savings are, relative to imaging in the country--

MR. KUHN. We have not--

MS. ESHOO. --and my other question is did you take into consideration the different costs relative to the setting of imaging? Hospital settings are always more expensive. They have greater overhead costs and a lot of other costs that are not attendant in a different setting.

So have you done that, and can you tell me about any kind of analysis that you have done relative to savings?

MR. KUHN. In terms of the savings and the offsets, the substitution of imaging for other procedures, I don't think we have done a detailed analysis that you are talking about here.

MS. ESHOO. Have you done any analyses?

MR. KUHN. There are a number of studies out there and we have begun to look in terms of the growth rates in these areas and the site of service shifts, but we don't have I think the level of detail that you are speaking to right now.

MS. ESHOO. Do you take into consideration, though, yes, there are growth rates, and I know in the healthcare system there is over-utilization, but sometimes I think that is where the over-emphasis is. Is there any kind of analysis that is done as to why there is the use that there is of the imaging? These are all advancements that we have made. Are we going to cut off the advancements because we don't want to invest in them? It seems to me that part of this debate is being driven by that, and that is really, I think, a march to folly on the part of our national policy.

MR. KUHN. There is a lot of technology advancements that nobody wants to stop. In fact, I think the last thing anybody would want to do to see any public policy stop some of the wonderful advancements have been there. But I think to put this kind of in a larger context, there are some other issues that people need to look at.

One is the enormous growth in this area. It is clearly there and I think that is going to catch anybody's eye when you see growth in a particular area like this, to be sure.

The second thing is the great variation that we are seeing. Glenn talked about some of the variation that they see. I recently looked at some numbers that talked about advance imaging, really the high-end computer assisted imaging, and I looked at four States. They were rural States, but they were Wyoming, Montana, and North and South Dakota. In Wyoming and Montana, the use of advanced imaging in those States was the high 50s, low 60 percent, but over in North and South Dakota, it was in the high 30 percent range. Great deal of variation in terms of use of these four neighboring States. What explains that, we don't know, but certainly you saw some higher utilization in a couple of States that are out there.

But the other thing that is driving us, too, again in terms of the overall context that people need to be thinking about, too, this is a key driver that is moving the SGR number in ways that are creating situations where having to maximize the cuts--

MS. ESHOO. I just want to interrupt for a second, because my time is just about up. Did CMS make this recommendation to conferees?

MR. KUHN. To my knowledge, this was not a recommendation coming from CMS.

MS. ESHOO. Thank you.

MR. DEAL. The gentlelady's time has expired.

Mr. Pitts is recognized for questions.

MR. PITTS. Thank you, Mr. Chairman.

How does MedPAC or CMS quantify the value of imaging? That is, how is imaging's cost-effectiveness valued? Is better treatment or a decreased need for surgery recognized? Many times, more than one imaging modality is necessary. For example, the immediate test for a stroke patient is a CT. It is fast, it is detailed. Once the patient is stabilized, MRI gives richer detail to make precise judgments about treatment. Do you evaluate volumes on a per patient basis, or do you count each encounter separately without describing the episode of services?

MR. KUHN. I believe under the particular program right now, we look at each individual's services. I think under current authority we cannot look at cost effectiveness in terms of procedures that are out there. We look at reasonable and necessary and whether they meet current program coverage rules, but in terms of cost effectiveness, that is not an existing authority Medicare has.

MR. HACKBARTH. We accept as a given that improvements in imaging can lead to better care, better outcomes for some patients, and there are numerous examples of that.

The proposition that we have looked at is that given that, is more imaging necessarily better for patients? And with help from researchers from Dartmouth, we have looked at care for particular categories of Medicare patients and looked at whether more imaging correlates with better outcomes. We found that the answer is no, more imaging does not necessarily correlate with better outcomes. That is not to say that all of the imaging is bad. Much of it is good, but there can be too much of even a good thing.

It is because of that complexity and how difficult it is to get a handle on this that we have treaded, I think, very lightly in terms of our recommendations with regard to the rising cost of imaging. Rather than recommending across the board cuts in fees for imaging, what we have said is that you need to start looking at some very specific issues. Are

we getting the prices right? Are we paying accurately for imaging services? We have recommended some coding edits to make sure that we don't basically pay twice for some types of services. We have recommended feedback to physicians on a confidential basis so they can understand their patterns of imaging and compare to their peers.

These are a far cry from well, let us slash, rising costs are bad, let us just save money. We have suggested some very targeted steps precisely because this is a very delicate complex matter.

MR. PITTS. To follow up, has, for instance, the use of ultrasound-guided breast biopsies reduced the number of invasive procedures or surgeries? Have you looked at how specific imaging services improve patient outcomes? Has CMS looked into the role imaging can play in efforts to lower the cost to the system by improving outcomes?

MR. KUHN. We have begun looking at this issue overall, I think, in aggregate. I don't think we have looked at this specific one, but yes, we are looking at those issues.

MR. PITTS. I am very concerned about potential impacts in reductions under the fee schedule. Have the consequences of imaging reimbursement reductions been examined? Has MedPAC or CMS contemplated the effect on beneficiaries? Is it possible that cuts will affect access, thereby contributing to late diagnoses leading to more invasive, intensive treatment? Is it possible that cuts will affect outcomes leading to poorer patient health or an increased number of unnecessary surgeries, or invasive procedures, leading to increased costs to the system?

MR. KUHN. When we put out a proposed rule, we will have impacts of a variety of natures in there for people to look at, and also we hope during that process we will be asking these kinds of questions so we can get the community at large to give us information to help us better understand the very questions that you are asking, Congressman.

MR. PITTS. Mr. Chairman, I have several other questions. I will just submit them in writing, if you can also respond to us within a couple of weeks.

Thank you.

MR. DEAL. Mr. Towns is recognized for questions.

MR. TOWNS. Thank you very much, Mr. Chairman. Let me also ask to place my statement in the record. I have an opening statement, but I was detained and was not able to be here. So I would like to ask permission to place that into the record.

MR. DEAL. I am sorry?

MR. TOWNS. I am seeking permission to put my opening statement in the record.

MR. DEAL. Without objection.

MR. TOWNS. Thank you.

Mr. Kuhn, what do you consider to be appropriate training for a physician to have in office diagnostic imaging services?

MR. KUHN. Right now under the Medicare law and rules, we defer to State licensure in terms of the appropriate training of determining what physicians can do within their scope of practice. So we don't tread or get in the way of State licensure in that regard.

MR. TOWNS. Let me ask you this. Do you feel there should be some standards, national standards?

MR. KUHN. I think right now the way we work through the system in terms of deferring to State licensure is working pretty well for the Medicare program. I think the direction that we would like to see the program go is we have been working very hard the last couple of years on this issue of trying to develop better quality standards or quality measures for payment purposes, and it gives us a chance to work with the specialty societies and others to use their evidence-based guidelines to translate those into quality metrics, quality indicators that we can use for payment in the future. I think driving the program in that direction will help us achieve the better results that we are all talking about here, while at the same time not having to go out and set separate individual standards that might be in place that have been talked about.

MR. TOWNS. I think this question was raised a little earlier, but I would like to go at it a different way.

Do you think that a reduction in payments to hospitals to deliver diagnostic imaging services under the Deficit Reduction Act will result in a significant drop in the delivery of these services?

MR. KUHN. It is a good question, and I don't think we know yet. That is why we hope when we put out our proposed rule we will have a greater and bigger opportunity to engage the stakeholder community to talk to us about those issues and get kind of a richer discussion about that issue through the notice and comment period.

MR. TOWNS. Because I feel that cuts might curtail access, and that bothers me because I think that is the last thing we need to do.

MR. KUHN. I couldn't agree more, and I think what Congress was trying to do in the Deficit Reduction Act was two things. One, I think they really did want to improve the quality of services and care that is out there. They did not want to impede access whatsoever, but they really wanted to get their arms around some of this growth that is out there that is fueling problems with the SGR, it is fueling issues with the Part B premium, and driving to, I think, some unsustainable growth rates that everybody needs to look at.

So all those things that we need to take into consideration as we put out our proposed rule that will be coming out soon.

MR. TOWNS. You know, I think that the provision of imaging services should be viewed in the context of fundamental changes in healthcare. Imaging is transforming the way that disease, illness, or injury can be detected and treated, and of course, I believe that imaging use should not be discouraged without a thorough understanding of its impact on the access and delivery of medical care, particularly in medically underserved areas.

So I am concerned about this. I know we are trying to cut costs and all of that, but at the same time, I think that we really have to be careful in what we are doing here.

Let me just raise this issue. In the medically underserved areas, have we had an opportunity to check to see where there has been a change in delivery of service since we have been using and you know it has increased a great deal?

MR. KUHN. I don't know whether CMS has looked in medically underserved areas in that issue or not. I could go back and check and we could get a response for the record, but I just don't know the answer to that question right now.

MR. TOWNS. Okay, because I am concerned whether or not the access situation, which is very important when it comes to the overall evaluation in terms of healthcare.

MR. KUHN. Right. I think you raised the point, and I think it kind of swings both ways. One, you want to make sure there is sufficient payments, that it is stable and reliable so that you encourage access in these particular areas. At the same time, you want to make sure that if we go the routes that have been talked about of creating standards, you don't want to create standards that are so problematic that providers won't come to those areas. So trying to find that balance between those two is going to be an absolute key in this area, as well as all parts of Medicare.

MR. TOWNS. Right. I see my time is expired, Mr. Chairman. Thank you. I yield back.

MR. DEAL. I thank the gentleman.

Mr. Pickering is recognized for questions.

MR. PICKERING. Thank you, Mr. Chairman.

It seems today the discussion is primarily around reimbursement funding and the degree that access is either improved or reduced, based on reimbursement. But the other question is to a degree that standards address both issues, that we can have the assurance that imaging technologies and services are being used in an appropriate way. Then it gives us greater confidence that the reimbursement and the sustainability of reimbursements can be met.

And so my question for Mr. Hackbarth is that we have an example of a successful standard in the Mammography Quality Standards Act, and in fact, in your testimony you used that as an example. I have introduced legislation, the CURE Act, broad bipartisan support and I believe Senator Enzi on the Senate side has a similar piece of legislation. Have you had a chance to review or look at either of those bills? We have set the standards in education and credentials, and would that be consistent with what you are recommending that Congress do? And have you any other comments or suggestions as it relates to those two pieces of legislation as to what we can do to then address all of the issues in a comprehensive way?

MR. HACKBARTH. Certainly, the legislation is quite consistent with the general thrust of our recommendations. We agree that it is important that there be quality standards. My recollection of your legislation is that it focuses not on the physicians, at least in the first instance, but rather on the staff that actually run the equipment. Is that right?

MR. PICKERING. It doesn't--whoever does the imaging, whether it is a technologist or the staff or the physician. It tries to take a neutral position, but to make sure that whoever is doing it is properly educated, has proper credentials, and does it in a proper way.

MR. HACKBARTH. Right, and so we agree on that. We think that there ought to be standards for both the physicians and the non-physician staff involved in the process.

Dr. Norwood raised the question earlier of who sets the standards, and what we have recommended is that Congress direct the Secretary of HHS to develop the standards and we think that the proper process for doing that would be to develop standards in close consultation with the relevant medical specialties societies, equipment manufacturers, and the like, people who have great expertise to bring to the table. So what we envision is not that people in HHS go off in a room by themselves and do this, but do it with people who have the relevant experience.

MR. PICKERING. Is that how the Mammography Quality Standards Act was done?

MR. HACKBARTH. That is my understanding of how it was done, yes.

MR. PICKERING. And that is an instance or example. We have had dramatic improvements in quality, reduction of errors--

MR. HACKBARTH. Yes.

MR. PICKERING. --and there is a greater confidence that the services provided warrant the reimbursements.

MR. HACKBARTH. Yes. The GAO looked at the issue of the impact of the Act on quality for mammography services, and they found a

significant decline in poor quality images and did not find a reduction in access to mammography services.

Again, I would emphasize that precisely because these services are so important and they are critical in making proper diagnoses and proper treatment that we have got to make sure that it is high quality work that is done. If poor quality imaging is done, then it can go off on the wrong path to the detriment of the patient, not to mention increase costs.

MR. PICKERING. So it would be fair to say that the Administration, as we look at reimbursement either reform or moratoriums, that the ability of Congress to pass legislation addressing standards in education and credentials, that you all would be supportive of those efforts and would want those to be combined, and to do it quickly before the end of this session?

MR. HACKBARTH. Well, as I said earlier, MedPAC has not looked at the DRA provisions regarding the rates for physician offices versus hospital outpatients, so we have no position on that, but certainly we would urge Congress to act quickly on legislation for quality standards.

MR. PICKERING. This year?

MR. HACKBARTH. As soon as possible.

MR. PICKERING. Thank you very much.

Mr. Chairman, I yield back.

MR. DEAL. Unabashed.

Dr. Burgess, you are recognized for questions.

MR. BURGESS. Thank you, Mr. Chairman.

I have got so many questions I want to ask, and I know, Mr. Kuhn, Dr. Norwood kind of already put you under a time deadline, so for the 2 weeks after that, could I get some questions answered?

MR. KUHN. We will do our level best to do them concurrently.

MR. BURGESS. And Mr. Hackbarth, I would claim the first 2 weeks, then, that Dr. Norwood didn't claim.

MR. HACKBARTH. He gave me some, too.

MR. BURGESS. Oh, he gave you--all right.

MR. HACKBARTH. We will shoot for 2 weeks also.

MR. BURGESS. I will extend the same courtesy, then, to MedPAC as I did to CMS.

The issues are complex, and I thank you both for acknowledging that. I really thank you for acknowledging what constraints we are under with the SGR and underscoring how important it is for us to address that fundamental flaw in the overall system. I hope, Mr. Chairman, we have a chance to do that.

Mr. Kuhn, in your testimony you note the rate of growth in different types of imaging. Do you have an opinion or do you have a sense of what proportion of that has been the growth in ultrasound?

MR. KUHN. I don't know if I have the specific numbers on ultrasound there. We could go back and look at the claims date and see if we can dig it out by specific area. What we do is we lump these together into kind of four general areas that we talked about earlier, advanced imaging, standard imaging, et cetera, but we could find the ultrasound information if you would like us to look for that.

MR. BURGESS. I very much would like that.

Now, as CMS develops regulations to comply with the provisions of the Deficit Reduction Act, will the standard of care be a significant component in the decision-making process?

MR. KUHN. We will have all that kind of information, all that kind of discussion will be in the proposed rule, and we will look at all the issues related to the DRA and put that out for everybody to comment, along with the impacts as well.

MR. BURGESS. Now, several people brought up the issue of defensive medicine and how that may be a driver in the growth of increased cost in medical imaging. You said that you didn't have that information. Is that because no one has looked for the information, or is the information somehow buried in all of the data that you have? Is that information that could be available to us, or would that require a new or separate study to be done?

MR. HACKBARTH. For MedPAC's position, we have not specifically looked at and tried to quantify what piece of the total increase is attributable to defensive medicine. I know that there have been some academics--

MR. BURGESS. How hard is it going to be for us to get that information, because I--

MR. HACKBARTH. It would be very difficult for us, because you are trying to understand what is in a physician's head when they are making a decision.

MR. BURGESS. Then if we can't get hard data, then I will fight anecdote with anecdote. I would submit to you that you can go into any emergency room in this country on Friday night after 11:00 p.m. local and say you have got the worst headache in your life, and you have just bought a CAT scan. I don't think you can get out of there without one. I would submit to you that anyone between the ages of 0 and 100 who walks into the emergency room that same Friday night after 11:00 p.m. and says I have pain in my abdomen is going to have a CAT scan to rule out appendicitis. The old days, we used to say that if a surgeon didn't occasionally remove a normal appendix, he was probably sending ill people home. That maxim doesn't fly anymore because everyone has the opportunity to have a CT diagnosis of their appendicitis. Dr. Norwood alluded to the problem with stroke diagnosis. At the risk of

oversimplifying, and as you both know, strokes can either be hemorrhagic or thrombotic, that is caused by a bleed. Brain damage can be caused by a bleed or it can be caused by a blood clot, but you have got vastly different treatments for each contingency as unfortunately, the former prime minister of Israel has shown us. He came in with a thrombotic stroke one day, appropriately anti-coagulated, but when it extended it was a hemorrhagic stroke. More anticoagulant didn't do him a bit of good, and it has left him in tough shape.

So these are aspects, I suspect, of this graph that you shared with us that we really need to know, because we are talking about where we come down with patient care on this. I lived through the same situation with my dad in 1989. He had a thrombotic stroke. In those days, we didn't have clot-busting medications available. Had they been available, that would have been very useful information to have, but had it been a hemorrhagic stroke, the TPA or endosceptilicin or whatever was administered would have been extremely damaging. We have the ability for--unlike my dad, who in 1989 had his stroke and was unable to talk for the next 18 years of his life, we have the ability today to take that same individual, break up the clot, and minimize their damage. And it is incumbent upon us to do that. Yes, we are going to be overtreating some people in the last 2 weeks of their life. That is just part of the bargain, as the lawyer the other day talked to us and said we deal with the world of competing sorrows. Those are some of the sorrows that we are just going to have to compete with. But unfortunately, you guys have to help us with this, and if that help is with data, I urge you to make that data available to us.

Again, I have got about 15 questions that I will submit for the record. Some very good thoughts about the issue of needle aspiration on breast diagnosis. If that has led to an increase in imaging, that has led to a decrease in cost. Again, we need to know that at this committee level.

Thank you, Mr. Chairman. I yield back.

MR. DEAL. I thank the gentleman.

Mr. Ferguson is recognized for questions.

MR. FERGUSON. Thank you, Mr. Chairman. I would ask unanimous consent that Dr. Burgess have to speak English.

MR. DEAL. Without objection.

MR. FERGUSON. I was feeling a thrombotic stroke coming on there for a second as I was listening to the questioning, for those of us non-physicians, particularly. You know, if you have a CAT scan I may need to take advantage of that. It does highlight the complexity of these issues, though.

First of all, thank you both for being here today. Mr. Kuhn, can you please explain the differences between the HOPPS based on APCs, and

the Medicare physician fee schedule which relies on relative value units? Specifically, is the HOPPS designed to capture the cost of performing an individual medical imaging procedure, and is it not true that the HOPPS system generally sets payment for an individual APC based on a median value of all the procedures included within that single APC, whereas the Medicare physician fee schedule seeks to establish a value for each individual component of a specific medical procedure?

MR. KUHN. You are absolutely right. On the outpatient side, it does set a median in terms of the data that we get, actual reports of claims data from the hospitals versus the physicians side, which is based on a fee schedule, which is based on survey information that is collected by the physicians goes to the relative value update committee, the RUC, and they look at this information and give us kind of relative values for those which is, you know, calculated differently.

So one is a perspective payment system, the other is a fee schedule. They are very, very different methodologies for computing payment rates.

MR. FERGUSON. Then it would seem that there is some question as to the appropriateness of using an HOPPS to cap payments for individual procedures done in an office setting. Would you agree with that?

MR. KUHN. I think you raise a good point, but a couple of observations I would just make, but I think it is worth for everybody to understand in that regard. One is at least on the outpatient setting we are getting actual claims data, actual information that is out there in terms of what this stuff costs, or at least the charges reduced to cost through cost to charge ratios as we move forward in that regard. And so I think that is one point.

The second is that you have great variation, great delta between the two different payment rates, and so I think what Congress was trying to do here in the DRA was to try to get a site neutral payment. Let us get the same kind of payment rate regardless of where the payment might be. And so I think that, too, is something that is worthy of Congress looking at.

But I think the other point, and I shared this earlier, is at least on the physician's side, we make an assumption that the equipment is used 50 percent of the time. What MedPAC has found in their research is that that is no longer the case. It is there is much higher utilization for the equipment. Likewise, in terms of information we are hearing from facilities around the country, it is much higher utilization rate than 50 percent. So basically the more you use it, the less it costs. And so it is not a direct linear line from 50 percent to, say, 75 percent or 80 percent, but when you have higher utilization rates, the two numbers in terms of

outpatient and physician match up pretty closely in terms of payment rates.

MR. FERGUSON. Well, I would just--and I have a question for Mr. Hackbarth as well, but when you initially were touching on--your initial part of your answer saying that this is a serious question. I mean, there is clearly a utilization issue that we need to get our arms around. There is a delta in the cost in reimbursement, and for these two things. And my sense is just using these two different, kind of very different ways of addressing similar procedures is troubling and probably isn't entirely appropriate. I am concerned with that and I hope we can further address that and continue to gather information from you.

Mr. Hackbarth, was what Congress included in the DRA package last year as it relates to the capping of payments for medical imaging procedures performed in the physician office setting, one of MedPAC's recommendations on a possible way to address the growth of Medicare spending on medical imaging?

MR. HACKBARTH. No, we did not look at that.

MR. FERGUSON. Well, the policy that we included in the DRA, will this really reduce--in your estimation, will this really reduce utilization, or does it have the potential to shift procedures to a hospital setting to encourage those physicians who own their own medical imaging equipment to perform a greater number of these procedures to make up for the lower payments as a result of the policy that we included in the DRA?

MR. HACKBARTH. Mr. Ferguson, we really have not studied it, so I wouldn't want to hazard a guess to its ultimate impact. As I said earlier, we have talked of a fairly conceptual level about a long-term goal for Medicare, which is to have the same payment rate regardless of site of service, and to try to set that payment rate at a level of an efficient provider of the service.

So at that very high conceptual level, I can understand where whoever came up with this DRA provision, what they were thinking about, but trying to operationalize that and translate that into real specific payment rates for a particular service is a difficult and important piece of work that MedPAC simply hasn't gotten into, so we don't have a stance on this particular provision.

MR. FERGUSON. My concern is clearly we were trying to address what we perceive to be as a problem, and I think many people acknowledge that there may well be a problem that needs to be addressed. My concern is that we may have slapped a solution on it or slapped a Band-Aid on this problem without really addressing the underlying issue, and we may, in fact, just be pushing the problem to a

different part of the health system rather than really getting at the heart of the problem. That is the basis for my question.

Mr. Chairman, I am out of time and I have managed to not have my thrombotic stroke, so I appreciate very much and I yield back.

MR. DEAL. Gentlelady, Mrs. Cubin, is recognized for questions.

MRS. CUBIN. Thank you, Mr. Chairman.

Mr. Kuhn, according to the American College of Radiologists, the cuts in DRA attributed to Section 5102(b) is 44 percent of the overall savings in the Medicare portion of the conference report. Would you agree with that or would you disagree with that?

MR. KUHN. I don't know if that is right number or not, but I think what everybody has kind of mentioned many times is that the imaging reductions were a large, significant part of the savings in order to deal with trying to make sure that physicians had a zero percent update for this year. That is correct.

MRS. CUBIN. Doesn't that seem--assuming, you know, plus or minus five percent, doesn't that seem like a disproportionate impact on one discipline, especially considering the imaging heavy physician services or practices?

MR. KUHN. A couple things. I think on its face when you look at it, it does look like a disproportionate number, but I think when you look at it in the larger context in terms of the growth rates we have seen in imaging over the last several years, how those growth rates have been contributing to the issues with the SGR in terms of hitting its maximum reduction that we impose with the statute and how that is also been contributing as a contributing factor to the increase in the Part B premium. I think when you take it in the larger context, I think it raises some good questions, but I think it also lets you see that there are needs for greater changes in the Medicare program if we are going to get our arms around growth in physician spending and deal with this Part B premium.

MRS. CUBIN. Well, I respectfully disagree with you because it seems to me that, just like Dr. Burgess referred to, a lot of money is saved from the increased practice of imaging. My son is in residency to be an interventional radiologist. I was lucky enough to sit in one day. A 53-year-old woman came in with a stroke. She couldn't talk, couldn't move one side of her body. Well, I was able to watch while they went in her carotid artery, and I don't know what they did with the clot in her brain, but an hour and a half later she was talking and moving her hand and her foot. Now, if they can't use the diagnostic tools that they need to be able to perform miracles like that, then the cost really is more. So I simply just disagree with you.

Prior to the Deficit Reduction Act, why was Medicare historically opting to operate under different reimbursement systems in terms of hospital and non-hospital imaging? Once again, I question whether the imaging cuts in the DRA fully account for those differences, and specifically, because the hospitals have the ability to cost share over a large volume of services and obviously the smaller practitioner doesn't. I fear very much that rural America and small cities, cities and towns like we have all over Wyoming, won't even have opportunities for CAT scans and MRIs the way things are going because nobody is going to invest in those except the doctors that use them, and then they are penalized for that investment and what the bottom line is, the patient doesn't get the care.

MR. KUHN. I think you are raising the question that many others on this panel have raised, and what we at CMS are going to struggle with as we move to implement this provision as we put out our proposed rule. How do we really do what Glenn has talked about earlier is make sure that we have efficient use of resources and we pay at the rate for the efficient provider, while at the same time making sure that we have uninterrupted access to care and that we have stability in the system so providers can count on it so they know they can make these investments and provide high quality care. It is a balancing act that we are all going to have to work through as we work through this provision, as well as others in the Medicare program.

MRS. CUBIN. Mr. Hackbarth, has there ever been a thorough assessment of how this reimbursement cut will impact Medicare beneficiaries and their access to care?

MR. HACKBARTH. Again, we have not looked at the impact of the DRA provision that would limit payment for imaging services in physician offices.

MRS. CUBIN. Well, it seems to me that access to care ought to be one of the most important considerations.

MR. KUHN. Access to care, for the Medicare program to work successfully, we have to have active, committed providers out there delivering care, and what they need is stability in terms of a payment system. They need predictability, and they need adequacy in terms of the payment, and we hope that as we work through this particular provision, work to implement it, we can do all those things.

MRS. CUBIN. I hope you can, too. Thank you.

MR. HACKBARTH. Just to mention one point about DRA. Almost all of the discussion about DRA is focused on the provision relating to limiting the payment for imaging services in physician offices. There is another provision in DRA related to imaging, and that is the one that reduces the payment for a second image using the same modality on a

contiguous body part, a fairly technical issue. But I want to be clear for the record that that is a provision that MedPAC has recommended, although we haven't looked at the other DRA provision.

MRS. CUBIN. Thank you.

MR. DEAL. If the gentlelady will allow me to share with her information that I have, the overall savings in the DRA under Medicare was $15.6 billion. Of that amount, $2.8 billion was in the imaging area. It encompasses both components that Mr. Hackbarth spoke about, and that is less than one-fifth of the overall savings in Medicare, and remembering this is an area that in the last 5 years had almost doubled in expenditures.

MRS. CUBIN. It sounds like there must be different things being considered for the American Radiologists Association to consider it a 44 percent cut, so there must be different things being considered. We will have to look into that.

MR. DEAL. Perhaps we will have a chance to do that during the second panel that is coming up.

But before we do that, we have a member of the full committee who has appeared here, and I would make a unanimous consent request on his behalf that Mr. Inslee be allowed to ask questions. Any objections? If not, Mr. Inslee, you are recognized for questions.

MR. INSLEE. Thank you, Mr. Chairman. I appreciate your courtesy.

Gentlemen, I want to ask you about a concern I have about lumping all diagnostic imaging into sort of one box. Particularly, I want to ask about ultrasound imaging. Let us just take an example of ultrasound-guided biopsies, breast biopsies. We know that ultrasound-guided breast biopsies, while they take two ultrasounds to do, they can have a decreased risk of infection, they can have a better cosmetic result, they can avoid some of the trauma associated with an open biopsy. But they do result in two extra diagnostic imaging that are going to show up in a databank that you have been reviewing.

From both of your perspectives, would you believe that that technique is a worthwhile valuable thing that we should not in some way punish or discourage in any of our rulemaking?

MR. KUHN. No question about that. I think rather than an open biopsy, if you can have an ultrasound to evaluate a lesion, it is far superior to be able to do it that way, and it is one of the real advances that technology has given us for better outcomes and better detection.

MR. INSLEE. Mr. Hackbarth?

MR. HACKBARTH. I agree with that. I have had a family member benefit from the procedure.

MR. INSLEE. So I guess the question I have is, is at least in some of the proposals I have seen, this sort of lumps ultrasound in with all of the

other diagnostic imaging techniques, and I just picked one, this ultrasound-guided biopsy, as one. There is a whole host--slew of ultrasound techniques. We will have a doctor talking about that later. Ultrasound guidance, central venous catheterization, that can have tremendously improved results. Ultrasound-guided aspiration of thyroid nodules, we have this whole host of techniques that will decrease trauma and decrease risk, and Mr. Hackbarth, you want to say something?

MR. HACKBARTH. I want to emphasize that within the category of ultrasound or almost any other--in fact, any other category of imaging that you can talk about, there are very important, very valuable procedures that help patients. I don't think anybody disputes that.

Having said that, there is research that we and others have done that shows that even with good things, more is not necessarily better. That is what makes this area so difficult. We are trying to, in a general category of good stuff, identify some problems, and there are problems.

MR. INSLEE. Right. And in doing so, wouldn't it make sense, given the distinct nature and attributes of these various diagnostic imaging techniques, to treat each one separately? If we treat them all the same, at least as I understand some of the proposals that are floating around here, they would all be treated the same. I am focusing on ultrasound imaging particularly. The center of some of the geniuses in the country happen to be in my district, so it is one of the reasons I am particularly interested in it, but I am sure there are others that have similar benefits.

Doesn't it make sense to treat--and I will just start with ultrasound--doesn't it make sense to treat ultrasound diagnostic imaging differently, designing rules that would be fitting to its benefits, to its advantages, both fiscally and physically? Wouldn't that make sense?

MR. KUHN. Absolutely. Within the Medicare program, to the extent that we can price and pay procedures as close to their actual costs, as Glenn indicated earlier, for efficiently delivered services, that is the ultimate goal for all of us. It is what we want to achieve here with this program. I couldn't agree with you more.

MR. INSLEE. So if you do agree with me, where does that lead? Are we going to go back and start to revise some of these proposals to--

MR. KUHN. I mean, obviously part of it is a staging process. I mean, how do you get to that kind of stage? Obviously, within the DRA provision what Congress was trying to do is put together here kind of a site neutral payment system. Why do we have this delta, this differentiation between the hospital outpatient and the physician service in their office? And so sometimes you have to take graduated steps to get where you want to get to your ultimate objective, but I think the key is what you are saying is let us pay as accurately as we can for each service. In the Medicare program, sometimes they are staged. As we

step forward, I think this particular provision in the DRA helps us kind of move forward in that staged process.

MR. INSLEE. As you do so, I hope you will pay particular attention to number one, the evidence suggests that ultrasound is growing at a slower rate, if at all, relative to other diagnostic imaging techniques, and that ultrasound just has these incredible advantages to the patient in reducing trauma, as well as being acutely sensitive. I hope you will think about that as you go forward.

MR. KUHN. Those are all good points, and hopefully those will be the kind of things that we capture when we put out our proposed rule and we really engage in the stakeholder community fully on these provisions.

MR. INSLEE. Thank you.

MR. DEAL. Mr. Green, do you have questions?

MR. GREEN. Yes, sir, Mr. Chairman. Thank you.

Mr. Kuhn, your testimony mentions that CMS currently assumes that imaging equipment is used 50 percent of the time, and your testimony also addresses MedPAC's assertions that CMS assumptions for payment of imaging services is too high and that MedPAC believes that equipment should be utilized more often, which would bring the cost for utilization per utilization down. Can you explain how CMS arrived at the 50 percent assumption?

MR. KUHN. Yes. My understanding on the 50 percent assumption goes back nearly a decade now. It was in a proposed rule, in a proposed regulation where we kind of engaged the physician community overall to talk about this issue, and at the end of the comment period, that is the number we came out. I don't think there was a lot of scientific information behind it, but I guess the best estimate at the time, best survey information people had at the time kind of pegged it at 50 percent. What we have seen, I think, over the past decade is a couple of things. One is a number of the groups that are doing this imaging activity in their offices and these independent facilities are coming in and sharing with us that their rates of utilization are exceeding 50 percent and much more aggressive. MedPAC, in terms of their comment letter to us last year on last year's proposed rule, also indicated that their research indicated that it was higher than 50 percent.

So I think it is something we have to look at pretty seriously.

MR. GREEN. Mr. Chairman, I agree, and I hope any further hearings we have, see if we can get some better numbers, because again, analogies don't make really good law. I know a lot of times in our major hospital facilities imaging equipment is used--I don't know if 24 hours a day, but probably 20 or 18 hours a day, because of the times. I know I have been there in the evenings in some of our facilities in the Houston area, so that is when they set appointments.

MR. KUHN. Yeah, and what we are seeing is more extended hours, weekend hours, and a lot of it is for patient convenience. People can't come in during the regular workday so they are going to come in the evening, so they are using this--I don't think inappropriately, to term services, but to get maximum use and provide convenience for the patient.

MR. GREEN. Okay.

Mr. Hackbarth, to follow up on Congressman Norwood's question about standards, we have also reported the intent on the Mammogram Quality Standards Act, and I am pleased that you referred to it as a potential model for imaging quality standards. What, if any, lessons have we learned from the Mammogram Quality Standards Act that we can use to implement effective imaging quality standards?

MR. HACKBARTH. Well, I think far and away the most important lesson is that it does work. It can work to improve the quality of service without having a severe detrimental effect on access. The standards can be developed in conjunction with professional societies. Again, I want to emphasize that that is the sort of process that we envision, engaging with the profession in what appropriate standards are, and that there ought to be different standards set for each of the various imaging modalities. So I think it is basically a success story. I am sure that as we were going through it, it wasn't all smooth sailing, but we think it is a good model.

MR. GREEN. Okay. Mr. Hackbarth, between 2000 and 2003, non-radiologist physician imaging grew 12 percent. During the same time, radiologist imaging grew 10 percent annually. MedPAC has recommended strengthening rules that restrict physician investment in imaging centers to which they refer patients; however, these statistics on their face suggest that perhaps the entire field has been growing and not just the non-radiologist imaging. Do these statistics relay a problem with physician investing in imaging centers, because one would think that over-utilization would lead to much greater growth in non-radiologist imaging?

MR. HACKBARTH. Well, the work that we looked at as a foundation in the prior recommendation is work done by the GAO and Inspector General and some academic research that shows that when physicians have an ownership interest, they, in fact order more images. How big that increase is depends on the modality. For some, like MRI, the number of images was doubled when the physician had an ownership interest.

MR. GREEN. Okay. Thank you, Mr. Chairman.

MR. DEAL. I thank the gentleman.

Thank you both, gentlemen. You have been here with good testimony. We appreciate your presence. I guess Dr. Norwood and Dr. Burgess are going to hold you to those timetables.

MR. KUHN. I am sure they will.

MR. DEAL. I ask the second panel to take their seats. Lady and gentlemen, we appreciate your being patient and waiting for the completion of the first panel. We are pleased to have you here and I will introduce you at this time. I would remind you, as I did the first panel, your written testimony has already been made part of the record. We would ask that the 5 minutes that you are allotted be a summarization of that, or other testimony that you may want to add in light of the testimony of the first panel.

We are pleased to have Dr. Pamela S. Douglas, who is the Chief of the Division of Cardiovascular Medicine at Duke University Medical Center; Dr. Arl Van Moore, who is Chairman of the Board of Chancellors of the American College of Radiology; Dr. Doug Laube, who is the President of the American College of Obstetricians and Gynecologists; Mr. John Donahue, President and Chief Executive Officer of the National Imaging Associates, Incorporated; Mr. Lynn May, who is the Chief Executive Officer of the American Society of Radiologic Technologists. Dr. Griffeth, I skipped you. I am sorry. My list and the sequence there is not the same. Dr. Landis Griffeth, who is the Director of Nuclear Medicine at Baylor University Medical Center; Mr. Robert Baumgartner, who is the Chief Executive Officer of the Center for Diagnostic Imaging in Minneapolis, Minnesota; and Dr. Donald W. Rucker, who is Vice President and Chief Medical Officer of Siemens Medical Solutions, USA, Inc. Once again, we are pleased to have you here and Dr. Douglas, we will begin with you.

STATEMENTS OF DR. PAMELA S. DOUGLAS, CHIEF, DIVISION OF CARDIOVASCULAR MEDICINE, DUKE UNIVERSITY MEDICAL CENTER; DR. ARL VAN MOORE, CHAIR, BOARD OF CHANCELLORS, AMERICAN COLLEGE OF RADIOLOGY; JOHN J. DONAHUE, PRESIDENT AND CHIEF EXECUTIVE OFFICER, NATIONAL IMAGING ASSOCIATES, INC.; DR. DOUG LAUBE, PRESIDENT, AMERICAN COLLEGE OF OBSTETRICIANS AND GYNECOLOGISTS; DR. LANDIS GRIFFETH, DIRECTOR, NUCLEAR MEDICINE, BAYLOR UNIVERSITY MEDICAL CENTER; LYNN F. MAY, CHIEF EXECUTIVE OFFICER, AMERICAN SOCIETY OF RADIOLOGIC TECHNOLOGISTS; ROBERT BAUMGARTNER, CHIEF EXECUTIVE OFFICER, CENTER

FOR DIAGNOSTIC IMAGING; AND DR. DONALD W. RUCKER, VICE PRESIDENT AND CHIEF MEDICAL OFFICER, SIEMENS MEDICAL SOLUTIONS USA, INC.

DR. DOUGLAS. I am delighted. Thank you, Chairman Deal.

MR. DEAL. Turn your microphone on and pull it where we can hear you.

DR. DOUGLAS. There, it is on.

Thank you, Chairman Deal. Members of the subcommittee, I am honored to testify before you today on behalf of the American College of Cardiology and the more than 20 healthcare organizations that comprise the Coalition for Patient-Centered Imaging. Together, we are united in the belief that office-based imaging is an integral component in the delivery of quality patient care, and should be protected as such. An extension of my remarks have been provided for the record, of course.

I am a Board-certified cardiologist and Chief of Cardiovascular Medicine at Duke University, but I am also the immediate past President of the American College of Cardiology, and the past President of the American Society of Echocardiography.

Today, patients, physicians, policymakers such as you, and payers are at a crossroads in debate over the provision of imaging services. The title of today's hearing aptly reflects what I believe is at the core of this debate. Ensuring that medical imaging received by Medicare patients is clinically appropriate. This subcommittee will hear from others and has heard this morning about why reductions in payments for office-based imaging services contained in the Deficit Reduction Act are bad policy and could negatively affect patient care. We agree, and therefore appreciate the commitment of many on the subcommittee have already made to reexamine DRA imaging policy and imaging quality in general in a more thoughtful, deliberate manner.

We recognize that Congress is concerned about the growth of imaging volume, but caution must be exercised to ensure that policies are driven by what is best for patients and not solely by budgetary constraints.

In keeping with the theme of today's hearing, I will focus my remarks on imaging appropriateness, which is an important component of imaging quality. Many physician specialties are using or developing tools, such as accreditation, training programs, guidelines, performance measures that foster quality in medical imaging. In my own specialty of cardiology, among groundbreaking quality efforts in imaging is the creation of novel appropriateness criteria, or diagnostic cardiovascular testing. The purpose of these is to address overuse, underuse, and misuse

of imaging tests. These criteria are patient centric and ask the question whether the right test is used for the right patient at the right time.

Last fall, the ACC and the American Society of Nuclear Cardiology published the inaugural set of appropriateness criteria for cardiovascular and nuclear imaging. The rigorous process for building the criteria included convening a panel of clinical experts, half of whom were not cardiologists, who assessed the benefits and risks of the procedure for different indications or patient scenarios. Using a RAND UCLA scoring method, the criteria for each indication were considered and given a designation of appropriate, inappropriate, or uncertain, in other words, not enough data. Subsequently, several private payers have adopted these appropriateness criteria and the College has achieved some success in getting radiology benefit organizations to update their guidelines to include these criteria. We hope that others, including CMS, will also consider their use through pilot projects. Meanwhile, the ACC will closely monitor how its appropriateness criteria are utilized to ensure that they are not misused to deny or delay care to patients.

The College will release appropriateness criteria for cardiac MRI and CT this summer and for echocardiography early next year. Ultimately, appropriateness criteria will improve cardiovascular imaging quality, weed out inappropriate utilization, and facilitate reimbursement for appropriate utilization in a performance-based measurement system.

But appropriateness criteria is just part of the bigger imaging quality picture. The College and other cardiovascular health organizations have been leaders in the development of laboratory standards and accreditation, training program standards, clinical competency statements, and clinical practice guidelines that contain recommendations regarding the necessary knowledge and skills and policies and procedures. With these threads of quality all pulled together, they culminate in improved patient outcomes.

To this end, this year ACC, in partnership with my own university, Duke, convened a 2-day think tank on quality in cardiovascular imaging with over 80 stakeholder participants, from payers, industry, professional societies, and government. The think tank mapped out a multi-year quality agenda to develop and implement standards as part of an action plan for cardiovascular imaging in general and each imaging modality in particular.

Ensuring the quality and safety of medical imaging is being accomplished through costly and painstaking work by professional medical organizations. Some have called for the implementation of Federal standards for imaging services. I want to emphasize that many such standards, including accreditation, certification, and quality improvement tools, already exist and should not be put into place as cost

containment mechanisms alone. It is important that the Federal government recognize specialty society efforts to ensure quality and safety, and not duplicate or override them by imposing non-specialty specific or overly burdensome requirements.

The Coalition for Patient-Centered Imaging and the American College of Cardiology are committed to working with Congress to responsibly address the growth in medical imaging. It is important that we all work together to ensure that Medicare beneficiaries are not denied access to appropriate imaging services that meet their healthcare needs, and that these are provided by quality physician specialists.

Thank you, and I look forward to answering any questions you have.

[The prepared statement of Dr. Pamela S. Douglas follows:]

PREPARED STATEMENT OF DR. PAMELA S. DOUGLAS, CHIEF, DIVISION OF CARDIOVASCULAR MEDICINE, DUKE UNIVERSITY MEDICAL CENTER

Chairman Deal and Members of the Subcommittee, I am pleased to testify before you today on behalf of the American College of Cardiology (ACC) and the Coalition for Patient-Centered Imaging (CPCI), an alliance of more than 20 physician specialty groups and health care organizations united in the strong belief that office-based medical imaging is an integral component in the delivery of quality patient care. I am a board-certified cardiologist and the Division Chief and Ursula Geller Professor of Research in Cardiovascular Diseases at Duke University Medical Center. I also serve as Director of Cardiovascular Research Strategy at Duke Clinical Research Institute. I am the immediate past president of the ACC and a past president of the American Society of Echocardiography (ASE).

I welcome the opportunity to offer the Coalition's perspective on the importance of office-based imaging and commend the Subcommittee for holding this hearing. Medical technology has evolved to provide crucial support to skilled patient care. Advanced technologies unheard of a decade ago are now key tools in the prompt and efficient diagnosis and treatment of patients.

We believe that patients, physicians, policymakers and payers are at a crossroads in the political debate over the provision of imaging services. The title of today's hearing aptly reflects what I believe is the core of this debate: Ensuring that medical imaging received by Medicare patients is in fact clinically appropriate. I expect that this Subcommittee will hear from others today about why reductions in payments for office-based imaging services contained in the Deficit Reduction Act (DRA) are bad policy and could negatively affect patient care. We agree with this assessment and appreciate the commitment many of you on this Subcommittee have already made to reexamine the DRA imaging policy in a more thoughtful manner, especially given the closed-door, eleventh-hour nature of this significant policy decision.

However, in keeping with the theme of today's hearing, I want to focus on the quality assurance tools that my specialty of cardiology and other physician specialties currently use -- or are developing -- to guide physicians in the appropriate ordering and performance of imaging tests. We firmly believe that until there are benchmarks for measuring appropriateness that will allow for a better understanding of imaging utilization growth, draconian approaches such as the one taken under the DRA will not only persist, but eventually negatively affect patient care and have no affect on utilization.

My testimony today will also highlight that imaging services, when provided by experienced and qualified physician specialists with training and experience, are important tools that vastly improve patient care. I also hope to provide a better context in which to view imaging growth.

Office-Based Medical Imaging Constitutes Good Patient Care

Advancements in medical imaging have changed the way cardiologists, urologists, orthopaedic surgeons, breast surgeons, obstetricians, neurologists, endocrinologists and other specialty physicians deliver patient care on a daily basis. Specialty physicians are uniquely qualified to provide imaging services specific to their specialty because they are trained in both diagnostic imaging techniques, and in the structure and function of the organs and systems they are imaging. By integrating medical technology into care plans, it offers the opportunity for earlier, better and more accurate diagnosis of disease or injury and the prospect of better quality care.

Today in cardiology, we are fortunate to have a wide range of non-invasive imaging techniques to combat and treat disease. With the selective use of echocardiography, nuclear imaging, CT and MR we can evaluate the heart to answer specific clinical questions presented by patients. This allows physicians like me to define the functional adequacy of the heart to pump blood in heart failure patients, or for my colleagues to assess the significance of plaque within a vessel wall by viewing it in three dimensions. We can now visualize what in the past required subjecting a patient to an invasive procedure. The ability to view various aspects of the heart is important to providing cost effective and minimally invasive diagnosis and risk assessment.

In addition to employing medical imaging for diagnostic purposes, physicians now use imaging to guide minimally invasive treatments and to track ongoing treatment protocols.

Two examples are ultrasound-guided needle breast biopsies and image-guided biopsies of prostate lesions. In breast surgery, ultrasound-guided breast biopsies in the physician office can be performed at a third of the cost and in about half of the time of an open surgical biopsy. Ultrasound-guided breast biopsy allows for less-invasive evaluation of mammographic lesions, with more reliable tissue differentiation, more streamlined patient care and characterization, and improved staging of disease. Patient satisfaction is also increased with shorter recovery times and minimized scarring. In addition to the clinical and patient satisfaction benefits, The Lewin Group estimates that use of image-guided core breast biopsies instead of open biopsies saved the Medicare program $88 million between 2001 and 2003.[1]

Urology offers another example where advancements in medical imaging have led to less-invasive and less-painful procedures. Older men often experience difficulty urinating because of prostate enlargement. To evaluate this problem, physicians must learn how much urine is retained in the bladder after voiding, known as "residual urine." For many years this was determined by passing a catheter through the urethra and into the bladder, the amount of urine drained from the bladder was then measured. Introducing a catheter into the bladder, in addition to being uncomfortable, also may introduce infection. Today, many urologists employ a small ultrasound machine designed specifically for this task. This test can be done in the urologist's office and eliminates the use of a catheter and the danger of infection.

The expectation of society, and of our patients, is that we will employ these marvels of medicine to achieve best practice outcomes for every care interlude. That means the integration of medical imaging as part of the treatment plan is here to stay.

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[1] "An Analysis of the Utilization of Ultrasound Imaging Services in the Medicare Program." The Lewin Group. May 2005.

Growth in Medical Imaging Utilization

There is no dispute that growth in medical imaging utilization is occurring. What is in dispute is how much of the growth is out of line with other Medicare Part B spending and whether increased utilization in imaging is creating cost savings elsewhere in the Medicare program. Last year the ACC commissioned a study by The Lewin Group to examine the growth in diagnostic imaging services.[2] Based on those study findings, we were and remain concerned that the Medicare Payment Advisory Commission (MedPAC) and the Centers for Medicare and Medicaid Services (CMS) continue to cite growth rates for imaging services without taking into account the shift in site of services out of hospitals and into physician offices. MedPAC, in its March 2005 report to Congress, acknowledged about 20 percent of the growth in imaging services paid under the physician fee schedule between 1999 and 2002 was due to this shift in site of services, but did not account for this shift in its growth comparisons.[3] Furthermore, MedPAC did not include all Medicare Part B services in its comparison of growth rates for imaging and other services. In particular, MedPAC omited durable medical equipment, chemotherapy drugs and other drugs covered under Part B, and ambulance services. Therefore, comparison in growth of imaging and the growth of other Medicare Part B services is distorted significantly. According to the The Lewin Group analysis, when all Part B services are included and the changes in the site of service are accounted for, imaging grew at an average annual rate of 11.2 percent from 1999-2004 compared with an average annual rate of 6.9 percent for all Part B services.[4] The increase in imaging utilization has resulted in particular scrutiny of advanced imaging such as CT and MRI. The Lewin Study found that these technologies had a higher rate of growth from 2003-2004, approximately 18 percent and 20 percent respectively, than other imaging technologies. The study also showed that radiology performed 84 percent of CT scans and 65 percent of MRIs.[5]

There are a number of reasons for the growth in imaging that are not adequately examined by MedPAC or CMS. The Coalition hopes that before further policy changes are considered, a more thorough analysis will occur as to the reasons behind the growth, including shift in site of service, clinical substitution, clinical appropriateness through the adherence to evidence-based scientific guidelines, advancements in technology, and demographic changes.

When growth is distorted, or factors for growth are not fully factored into an analysis, it leads to inadequate and/or inappropriate policy responses.

Responding to Medical Imaging Utilization Growth

As I mentioned in my introduction, patients, physicians, private payers and the federal government are all caught in the middle of political debate over the growth and future of medical imaging. The DRA cuts enacted this year are just one example of several onerous responses to imaging utilization growth. Proposals set forth by MedPAC include setting federal standards for accreditation of facilities and certification of individuals. I will tell you today that these measures are not, and should not, be viewed as cost-containment mechanisms. They are tools to improve quality – a point I will elaborate on later in my testimony.

Cuts in Medicare Reimbursement for Medical Imaging Services

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[2] "Issues in the Growth of Diagnostic Imaging Services: A Case Study of Cardiac Imaging," The Lewin Group, May 3, 2005.

[3] Report to Congress: Medicare Payment Policy, MedPAC, March 2005.

[4] "Issues in the Growth of Diagnostic Imaging Services: A Case Study of Cardiac Imaging," The Lewin Group, Report Addendum, June 20, 2005.

[5] "Issues in the Growth of Diagnostic Imaging Services: A Case Study of Cardiac Imaging," The Lewin Group, May 3, 2005.

Earlier this year, as part of the DRA, Congress enacted a provision that cuts payments for many office-based imaging services. The law requires that Medicare payment for the equipment, supplies, non-physician personnel, and overhead associated with non-hospital imaging services *(the technical component)* be paid, effective Jan. 1, 2007, at either the Hospital Outpatient Prospective Payment System (HOPPS) rate or the Medicare physician fee schedule amount, whichever is lower. This provision was included in neither the House nor the Senate deficit reduction bills, but emerged from conference committee and was enacted without ever having been subject to public comment or scrutiny.

Not surprisingly, the DRA will result in draconian payment reductions for some imaging services in non-hospital settings. For many of those services, anticipated reductions as a result of the DRA are in the range of 35-55 percent. For example, Medicare payment for ultrasound guidance procedures performed as part of minimally invasive biopsies for the diagnosis of breast cancer would be reduced by 35 percent; Medicare payment for positron emission tomography (PET)/CT exams used to diagnose cancerous tumors and to determine the effectiveness of cancer treatment would be reduced upward of 50 percent; and payment for bone densitometry studies to diagnose osteoporosis (a recently added Medicare screening benefit) would be reduced by more than 40 percent.

The Coalition is troubled by the precedent-setting nature of this provision. Nowhere else in Medicare are physician payments tied to hospital outpatient reimbursement. The methodologies used to determine payment rates for hospital and non-hospital imaging services are based on different data and different methodologies. Therefore, if the methodologies and data differ, why would Congress require that a methodology used to determine reimbursement in one setting be used to set reimbursement in a different setting for the same service? If Congress' intent was to "level the playing field" for imaging reimbursement, payments for office-based imaging services that are lower than the hospital outpatient rates should be increased. What is clear is that the policy was built less on strong or sensible policy rationale and more on the need to create savings to offset other spending. While the physician community appreciates Congress' intervention to stop a negative update in Medicare physician payments this year, the zero-sum politics of physician payment is unsustainable.

The DRA medical imaging cuts cannot be considered in isolation. There are other policy changes that will or could negatively affect medical imaging reimbursement in 2007. As part of the DRA, Congress imposed a multiple procedure discount to selected diagnostic imaging procedures. Eligible procedures were identified and grouped into 11 "families" of related CPT imaging codes. For these procedures, Medicare will make full payment for the procedure with the highest payment rate and then apply a 50 percent reduction in the payments for second and subsequent imaging procedures in the same family that are performed during the same session.

Most recently, CMS published a proposal to completely revamp the methodology used to determine the physician fee schedule technical component and other physician practice expenses. This proposal will affect imaging technical component services, but impact varies by services.

While such payment reductions may result in short-term savings, there is no evidence that decreasing payment rates will reduce any inappropriate utilization. However, Medicare cuts such as those highlighted above, not to mention the pending 4.6 percent across-the-board cut, are likely to result in reduced Medicare patient access, higher beneficiary co-payments, and lower quality due to the reduced availability of funds for imaging equipment maintenance, replacement, and upgrades.

According to an online survey conducted May 24-June 21, 2006 by CPCI of more than 3,900 individual physicians, practice administrators, and health care professionals across the country, 40 percent of those who had planned to purchase or lease new

imaging equipment in 2006 or 2007 delayed or canceled those plans largely due to the DRA cuts.[6] While this may sound like good news to payers, it provides no relief to Medicare patients who already endure long waits for imaging services. According to a study recently conducted by the Society for Vascular Ultrasound, on average, patients already wait 10 days to two weeks for non-urgent imaging services in the hospital outpatient department. If Medicare reimbursement for medical imaging services decreases in 2007, 47 percent of respondents said they will cut practice overhead by reducing personnel levels, compensation or fringe benefits; 46 percent say they will discontinue value-added but non-reimbursed patient services; 44 percent will freeze or delay hiring of clinical staff; 40 percent will delay the purchase or updating of electronic medical record software; and 39 percent will no long provide imaging services to Medicare beneficiaries.

When asked where patients would go to receive imaging services if they were no longer provided in their office, the respondents replied that 83 percent would be sent to hospitals for those services. According to the American Hospital Association, the demand for hospital care, both outpatient and inpatient, is rising and half of emergency departments are "at" or "over" capacity.[7] If medical imaging becomes a fiscally unsustainable service for physician practices or if restrictive standards or regulations are imposed, patients will be forced into already over-crowded hospitals to receive imaging services. Medicare patients who must go to the hospital outpatient department to receive imaging services may not only endure significantly longer wait times, delayed diagnosis and treatment, but their co-payments will also jump from 20 percent in the physician office setting to up to 40 percent of charges in the hospital outpatient department setting.

Federal Standards for Office-Based Imaging

Some policymakers have called for the imposition of federal "standards" as a mechanism to increase quality and safety in the provision of imaging services. It is likely that under such a regulatory scheme, nationally-based imaging norms would be developed, implemented and administered by CMS and would apply to both the technical (e.g., equipment/overhead) and professional components (e.g., interpretation of the imaging) of imaging services.

We do not oppose the use of criteria that foster and support better quality and safety of diagnostic imaging, but we caution against the federal government's having a role in this realm. The federal government has not played a part in the credentialing and determination of privileges of physicians to provide medical services. Typically, the practice of medicine has been left to the states to govern. States most commonly rely on the expertise of medical professional organizations or boards to create standards, guidelines, or other criteria for their members. The development and imposition of federal standards on the practice of medicine would represent an enormous new role for Congress and CMS that could lead to the politicizing of medical privileging – physician organizations would incessantly "lobby" the federal government on medical scope of practice and other, similar matters, most appropriately left for the states to decide.

To be candid, inherent in this discussion are "turf" issues as well as concerns about increased utilization and appropriateness of testing. Some, notably in the radiology community, have mounted criticisms based on quality of diagnostic services performed by non-radiologists. They seek to set standards that would effectively allow only radiologists to perform and interpret images and bill Medicare for their services, particularly in certain "advanced" modalities, such as CT, MR and PET. Yet, there is no

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[6] Coalition for Patient-Centered Imaging. Online survey of physicians, practice administrators, and health professionals conducted May 21-June 24.

[7] "The State of America's Hospitals – Taking the Pulse." American Hospital Association. 2006 AHA Survey of Hospital Leaders.

credible evidence to demonstrate systematic quality problems in performance and interpretation of diagnostic medical imaging by specialists who are not also board-certified radiologists.

Federal quality/certification regulations or thinly veiled attempts to protect "turf" will not lower utilization, but will merely redirect it. Nor do such regulations address the challenge of ensuring that the right test is provided by qualified personnel in the right setting, at the right time. Ensuring the quality and safety of medical imaging can only be accomplished through costly and painstaking work by the professional medical organizations who are meeting the challenge by developing training programs and requirements, appropriateness criteria, guidelines, and other quality-improvement tools such as performance measurements. Medical organizations are at different stages in their development of these types of tools. Nevertheless, it is appropriate that these efforts be specialty and modality specific and have significant input from the respective specialty organization(s).

Ensuring Appropriate Use of Medical Imaging Tests

The ACC, the American College of Surgeons (ACS), the American Academy of Orthopaedic Surgeons, the American Association of Clinical Endocrinologists, and other specialties are making strides in developing and using tools including accreditation and training programs, guidelines, and performance measures, that will facilitate the delivery of quality and appropriate imaging services. For instance, large multi-specialty medical groups utilize practice guidelines – whether related to chronic diseases like diabetes or imaging services. Requiring these large providers to adopt a national, one-size-fits-all standard that overrides carefully considered care management processes within the group setting makes little policy sense.

American College of Cardiology

Cardiology is a leader within the imaging community in the development of quality-improvement tools, largely because of the dependence upon imaging in the provision of cardiac care. Among the ACC's quality efforts is creation of groundbreaking appropriateness criteria for diagnostic tests. The purpose of appropriateness criteria is to address overuse, under use, and misuse of imaging tests. These directives are patient-centric and define "when to do" and "how often to do" a given procedure in the context of scientific evidence, the health care environment, the patient's profile and the physician's judgment.

In October 2005, the ACC and the American Society of Nuclear Cardiology (ASNC) published its inaugural set of appropriateness criteria for Single Photon Emission Computed Tomography Myocardial Perfusion Imaging (SPECT MPI), commonly known as cardiovascular nuclear imaging. To build the criteria, a representative panel of clinical experts met to assess the benefits and risks of the procedure for different indications, or patient scenarios. The panel used the RAND/UCLA appropriateness method to score each indication, assigning scores within a range of one to nine. Using these scores, the panel identified for each indication whether SPECT-MPI was appropriate, inappropriate or possibly appropriate requiring more patient-specific information. This process and methodology is being used by the ACC to develop appropriateness criteria for cardiac MR and CT and echocardiography, scheduled for release this summer and early 2007, respectively.

Not only do appropriateness criteria promote safe and cost-effective cardiovascular care, these criteria also can help ensure the delivery of more equitable health care among all demographic profiles, minimizing documented disparities. Several third-party payers have adopted the SPECT-MPI appropriateness criteria for diagnostic imaging and the ACC has achieved some success in getting radiology benefit management organizations to update their guidelines to include the SPECT-MPI appropriateness

criteria. The ACC is closely monitoring how the appropriateness criteria are utilized to ensure that they are not misused.

To facilitate the adoption of its appropriateness criteria, the ACC is working with the Oklahoma Foundation for Medical Quality, the OK Quality Improvement Organization (QIO), to develop a project proposal based on a recently issued CMS QIO RFP titled "Developing a Framework for Improving Outcomes via Curtailing Harmful Over-Utilization for Chronically Ill Beneficiaries." The proposed project would focus on appropriate utilization of SPECT MPI for cardiovascular patients using the ACC/ASNC SPECT MPI appropriateness criteria. Among the objectives are establishing regional variations in annual volume and growth rates for SPECT MPI, as well as the potential impact of a prospective ordering sheet to foster quality improvement and benchmarking based on the appropriateness criteria.

Already physicians are using the SPECT MPI criteria, allowing them to compare their practice patterns with those of their peers. Ultimately, appropriateness criteria will weed out inappropriate utilization, improve imaging quality and facilitate reimbursement in a performance measurement-based system.

Quality in cardiovascular imaging will require us to adopt new processes for quality improvement. A thorough and thoughtful process must be put in place for measuring quality that begins before the patient even walks through the door. Early this year, the ACC, in partnership with the Duke University Medical Center, convened a two-day Think Tank on Quality in Cardiovascular Imaging with 80 stakeholders representing imaging professional societies, academics, quality experts, CMS, FDA, private payers, equipment manufacturers and pharmaceutical companies. The think tank mapped out a multi-year quality agenda to develop and implement standards as part of an action plan for each imaging modality. These plans include development of patient selection criteria, as well as protocols for measuring the quality of laboratories, image acquisition, image interpretation, communication of results, and improved patient outcomes. The summit proceedings represent a consensus of the leadership of the ACC, American College of Radiology and a host of cardiovascular specialty organizations and will be published in the *Journal of the American College of Cardiology* later this year.

American College of Surgeons

To ensure that surgeons who use ultrasound are qualified and that the ultrasound facilities and equipment they use are appropriate for the medical application and meet and maintain quality standards, a thorough verification program was developed by the ACS for surgeons and surgical residents. The program provides a formal means of education verification to assist in credentialing. Through didactic instruction, practical demonstration, and hands-on sessions, the ACS "Voluntary Verification Program for Surgeons in the Use of Ultrasound" provides advanced knowledge of clinical applications tailored to specific types of surgical clinical practice, including acute/trauma, vascular, breast, abdominal, intraoperative/laproscopic, and head/neck.

The ACS has also developed the "Stereotactic Breast Biopsy Accreditation Program" to ensure that only qualified personnel perform stereotactic breast biopsies for the diagnosis and treatment of breast cancer and appropriate equipment is used to ensure that women receive optimum tissue sampling with the lowest possible risk. The program offers physicians the opportunity for peer review and comprehensive evaluation of their facility's staff qualifications, equipment, quality control and quality assurance programs, image quality, and breast dose. Those facilities successfully meeting all of the criteria are given a three-year accreditation and the American Cancer Society, the National Alliance of Breast Cancer Organizations, National Cancer Institute, Y-ME and other patient referral organizations are provided with an updated list of accredited facilities.

The American Academy of Orthopaedic Surgeons

The American Academy of Orthopaedic Surgeons (AAOS) has established quality guidelines to enhance orthopaedic surgeons' diagnosis and treatment of various musculoskeletal conditions. Workgroups consisting of members of AAOS and Orthopaedic Specialty Societies, with scientific and clinical expertise, were organized to create the guidelines. Workgroup members attended workshops to learn how to develop, evaluate, and revise evidence-based guidelines. They created "decision trees" or algorithms for treating knee and shoulder pain, common orthopaedic conditions. In each algorithm, suggestions for the most effective and efficient imaging options, based on the patient problem, standards of care, and the advantages and disadvantages for using each imaging modality help orthopaedic surgeons make an accurate diagnosis and treatment plan. Additional guidelines are under development to ensure appropriate patient care, including the appropriate use of imaging technology, for all orthopaedic conditions.

In addition, more than half of all orthopeadic surgeons have a formal rotation in radiology during training. Orthopaedic surgeons cannot become board certified physicians without passing an exam of which half of all questions on part one and all of the questions on part two require the interpretation of an image.

American Association of Clinical Endocrinologists

The American Association of Clinical Endocrinologists (AACE) and the American College of Endocrinology (ACE) have long recognized the need for specialized education and training to verify knowledge, skills, and capabilities in endocrine imaging services.

Since 1998, the AACE and ACE have sponsored the Thyroid Ultrasound and FNA Biopsy Accreditation Course®. Physicians who successfully complete this course have the indications and limitations of thyroid ultrasound and how it integrates with other thyroid tests to improve the diagnosis and management of thyroid disease. Physicians successfully completing this course and examination receive a certificate of accreditation for Thyroid Ultrasound & Ultrasound Guided FNA Biopsy. Ultrasound is an example where a highly skilled endocrinologist or other qualified physician can utilize real time ultrasonography to optimize and facilitate excellence in patient care, procedures and outcomes.

AACE and ACE also sponsor Endocrine University®. Endocrine University® provides specially designed curriculum and programming to help prepare endocrine fellows for entering clinical practice. Endocrine University® is held once a year and is open only to final year fellows-in-training in endocrinology. The course is held at the Mayo Clinic in Rochester, Minn., and provides fellows with an intensive six-day curriculum which covers thyroid ultrasound accreditation, bone densitometry accreditation, Metabolic Laboratory CLIA certification, practice management topics, and insulin management.

It is important that the federal government recognize and not duplicate or override specialty society efforts to ensure quality and safety by imposing non-specialty specific requirements. There are already a number of specialty-specific programs designed to improve imaging quality, as well as state laws and regulations in place that stipulate equipment quality controls and technologist training requirements. Specialty society efforts should be encouraged and quality related initiatives for diagnostic imaging should be considered by Congress in the context of broader pay-for-performance concepts.

June 2006 Medicare Payment Advisory Commission Recommendations

As Congress considers policy proposals that relate to medical imaging, we hope that you will consider what further cuts in medical imaging services will do to quality-improvement efforts. The passage of the DRA imaging cuts sent a message to the physician community that Congress cares more about ratcheting down costs than

improving quality. Continued cuts of this nature will have an absolute stifling effect on quality improvement efforts by the physician specialty community.

The Coalition is concerned with a recommendation in MedPAC's June 2006 Report to Congress that CMS adjust the equipment utilization assumption used in physician practice expense payment calculations upward from 50 percent. Such an adjustment could severely affect payments for office-based imaging services at a time when imaging is already poised for reimbursement cuts. MedPAC's recommendation, that would be applicable to all imaging services, was based predominately on a study of MRI and CT utilization. We hope that the Committee understands that the ultrasound equipment use rate is likely to be different from the utilization rate of an MRI machine because of the practice patterns of the specialties that use each type of imaging modality. For example, ultrasound services are one element of the clinical care provided by many specialties and, as such, are used as an adjunct to the practice of many physicians whose primary occupation is direct patient care – i.e. surgical procedures and office visits. MRI and CT, on the other hand, are more often used in a radiology practice setting as the only type of care provided, and thus are less likely to be idle during business hours.

We request caution on the part of Congress and CMS and ask that MedPAC be directed to expand its survey to collect data using a large, broad-based sample which includes different equipment types across all sites of service, distinguishing by specialty before changes in equipment utilization rates can be considered for equipment in non-hospital sites of service. Because of the limitations of the MedPAC study, it would only be prudent at the present time for MedPAC or CMS to propose adjustments in utilization assumptions for free-standing imaging facilities that have billed Medicare for CT and MRI services.

Also in MedPAC's June 2006 report, it concluded that the assumption of 11 percent in calculating the cost of capital for medical equipment purchases is too high. MedPAC arrived at this conclusion based upon a review of Federal Reserve Board information on commercial loans, but with the admission that a more specific source of data on the subject had not been located. The Coalition disagrees with this conclusion and believes that if MedPAC staff were to survey financing companies that lend money for medical equipment purchases, their conclusion may be different.

The Coalition was able to obtain information from Key Equipment Financing regarding the current and expected future cost of capital. KeyCorp, the parent company for Key Equipment Financing, is one of the nation's largest bank-based financial services company. For more than 20 years, Key Equipment Finance has been providing financing to health care providers including medical doctors, clinics, group practices and hospitals. The information from Key Equipment Financing indicates that rates for long-term leases/purchases for imaging equipment have ranged from 8-10 percent over the last few years, but that these rates are abnormal and have been the result of historically low prime rates. However, with the recent actions by the Federal Reserve to raise the base interest rates that banks pay to borrow money, the interest being charged today on new long-term leases is expected to be between 9-11 percent, depending on the amount of money borrowed.

We believe that this information validates that CMS' estimate for the cost of capital continues to be a correct assumption and is not in need of adjustment. Therefore, we recommend the Subcommittee direct MedPAC to investigate the issue more fully, directly surveying medical equipment financing companies before they or CMS move forward with recommending any changes to this aspect of the formula for calculating practice expense payments for equipment under the Medicare physician's fee schedule.

Conclusion

The organizations that comprise the Coalition for Patient-Centered Imaging are committed to working with Congress to responsibly address the growth in medical

imaging. It is important that we all work together to ensure that Medicare beneficiaries are not denied access to appropriate imaging services provided by qualified physician specialists. Thank you for the opportunity to present our views. I look forward to answering any questions you may have.

MR. DEAL. Thank you. Dr. Moore.

DR. VAN MOORE. Thank you, Chairman Deal, for the kind introduction. I thank Congresswoman Myrick for the introduction as well.

I thank you, Chairman Deal and the subcommittee members, for recognizing the important role that medical imaging serves and quality care provide to Medicare beneficiaries. I particularly thank those 56 Members of Congress, 15 of whom are on this subcommittee, for cosponsoring H.R. 5704 introduced by Congressman Pitts. The legislation calls for a 2-year delay in implementation of Deficit Reduction Act imaging cuts and a GAO study regarding their effect on patient care.

While ACR understands Congress' need to make difficult budget decisions, Section 5102(b) of the DRA is troubling to the College. This policy requires CMS to reimburse the technical component of in-office imaging at the lower of the Medicare fee schedule rate, or the HOPPS rate, the hospital outpatient perspective payment system rate. The HOPPS was never intended to accurately reflect costs at the procedure level. For example, hospital reporting systems may not uniformly delineate capital equipment costs. ACR believes picking and choosing between payment systems based on whichever is cheaper both invalidates and corrupts both systems, not only for imaging services, but for all of medicine. Until a substantive review is completed, implementation of the DRA should be delayed, as proposed under Congressman Pitts' bill.

Furthermore, the DRA policy does not address imaging utilization. Physicians who refer patients to their own equipment can take advantage of this policy and recover losses by ramping up volume, the exact opposite that the Congress intended. These cuts, when applied in tandem with ongoing CMS rulemaking reductions, may force physicians to limit the number of patients in the Medicare system that they accept. As a result, Medicare beneficiaries may be forced to endure increased wait times and increased travel times, particularly in rural areas.

The College has echoed many previous MedPAC recommendations for mandatory quality and safety standards for all imaging providers that will be determined by the Secretary of HHS. MedPAC called for all imaging providers, regardless of specialty, to meet Federal standards regarding physician training, equipment maintenance, and certification of non-physician staff.

Clearly, quality standards have government precedent. In 1992, Congress enacted the Mammography Quality Standards Act, or MQSA. This program sets standards for the facility, the technical staff, and physicians involved in mammography. It has unquestionably improved breast cancer diagnosis and has reduced the breast cancer death rate. Physicians have adapted to these MQSA standards. Technology clearly continues to advance, and more importantly, the level of care has greatly improved. Our patients, your constituents, have benefited.

Another example of Federal imaging standards is CMS regulation of independent diagnostic testing facilities, or IDTFs. CMS currently gives States the authority to regulate IDTFs. Some States are diligent in this overview; unfortunately, others are lax. ACR maintains that CMS currently has the authority to assert national quality and safety standards for all imaging providers, and expand their IDTF requirements to all settings. If this were done, uniform quality and safety standards usually associated with hospital and radiology practices will be required for all physicians performing imaging in the office setting.

To improve imaging quality and to reduce costs, many private insurers have implemented accreditation programs similar to those proposed by MedPAC and the ACR. Insurers recognize that accreditation is a key element in evaluating and maintaining quality and safety for their patients. Any one of these programs will one, improve the quality of imaging services for Medicare beneficiaries, and two, achieve the savings that the DRA was intended to capture. Given the likelihood that Medicare spending over the next 10 years on the highest cost modalities will approach $100 billion, deterring just 5 percent of projected spending would save Medicare $4 to $6 billion over the next decade.

Embracing the ideas that we have articulated will benefit patients and the healthcare system, which is our goal. And it will significantly reduce expenses, which is one of your goals. I urge this subcommittee, as well as the entire Congress, to enact H.R. 5704 and to implement sensible imaging reimbursement policies, such as those that I have discussed today.

On behalf of the more than 32,000 members of the ACR, thank you for your time and attention. I look forward to any questions you might have.

[The prepared statement of Dr. Arl Van Moore follows:]

PREPARED STATEMENT OF DR. ARL VAN MOORE, CHAIR, BOARD OF CHANCELLORS, AMERICAN COLLEGE OF RADIOLOGY

Chairman Deal and Distinguished Members of the Subcommittee,

My name is Arl Van Moore, Jr., M.D. and I am the Chair of the Board of Chancellors for the American College of Radiology. I am a practicing radiologist from Charlotte, North Carolina. It is a pleasure and an honor to represent the more than 32,000 members of the American College of Radiology before this distinguished body.

The College is the nation's largest radiology specialty organization representing diagnostic radiologists, radiation oncologists, interventional radiologists, nuclear medicine physicians and medical physicists. Our goal remains to advance evidence-based criteria to support the delivery of higher quality, safe, appropriate and cost-effective diagnostic imaging services. Today, I will be discussing the imaging provisions contained in the Deficit Reduction Act of 2005 (DRA), their impact on providing imaging services to Medicare beneficiaries and the College's recommendations for addressing the rapid growth in utilization of imaging services in Medicare through the establishment of quality and safety standards.

I would like to thank Chairman Deal and the Members of the Subcommittee for holding this hearing and recognizing the important role medical imaging plays in the quality of care provided to Medicare beneficiaries. I especially want to thank those Members of the subcommittee who are already cosponsors of HR 5704, the Access to Medicare Imaging Act of 2006, introduced by Congressman Pitts. This legislation calls for a 2-year delay in the implementation of the DRA imaging provisions in order to allow for a GAO study to examine the potential effects on Medicare beneficiary access to the latest medical imaging technology and procedures. I believe these cosponsors' participation underscores the importance of this issue and would encourage other Members of the subcommittee and full committee to become cosponsors.

Furthermore, I would like to state that the ACR is proud to be a founding member of the **Access to Medical Imaging Coalition (AMIC),** a broad alliance of patient advocacy groups, medical manufacturers, and providers. As one of several AMIC members testifying today, ACR fully supports the enactment of 5704.

DRA Concerns

The ACR continues to encourage and support the technological innovations and advances in diagnostic medical imaging, which have unequivocally improved the quality of patient care while producing cost savings through less invasive diagnostic techniques. As medical physicians who have devoted over 75 years to the study, and practice of the science and clinical application behind imaging technologies, the ACR and its members' training, expertise and passion is focused on medical imaging. As a result, we have serious concerns regarding the affects that the severe reimbursement cuts contained in section 5102(b) of the DRA will have on the provision of imaging services to our Medicare patients.

ACR fully understands Congress' need to make difficult budgetary decisions to maintain the solvency of the Medicare trust funds and we have always been willing to work with Congress to develop reasonable policies to accomplish this mutual goal. However, the College has some serious concerns with the policy contained in section 5102(b) which arbitrarily applies the hospital outpatient payment system and does little to neither address the issue of utilization nor improve the quality of the care provided to Medicare beneficiaries. Some examples of imaging procedures and the severity of their cuts include:

- CT angiography to examine heart arteries - reduced by 50 percent;
- PET/CT exams to pinpoint tumor location - reduced by 50 percent;
- MRI of the brain which is used primarily to diagnose brain tumors - reduced by 50 percent;
- MRI of the abdomen which is used to diagnose abdominal and/or liver cancer - reduced by 48 percent; and

- MR angiography of the head which is used to detect the location of aneurysms - reduced by 42 percent.

The College finds it hard to believe that the Congress and Members of this subcommittee were aware that this policy would result in such dramatic cuts in the payment of such vitally important medical imaging procedures. In addition, reimbursement policies that pick and choose between payment systems based primarily on the budget savings available to be achieved without validating the accuracy of either system or examining the applicability of either system corrupts and invalidates both payment systems.

ACR's concerns with the DRA imaging provisions fall into two basic categories; the policy setting process of the Conference Committee of the DRA and the actual imaging reduction policy that was enacted. When a provision is offered to the Conferees which results in a $2.8 billion direct reduction in physician fees, one would hope that such a provision would be debated in committee, on the House or Senate floor or be the subject of a study by an outside federal agency as to the effects of such a policy. Regrettably, none of this oversight occurred with regard to section 5102(b). We think the results of this inaction during conference resulted in a policy that subjects and singles out a particular range of physician services to severe reimbursement reductions that are unfounded, and fails to address, in any way whatsoever, concerns Members of Congress may have about the appropriate and safe use of complex imaging tests on our Medicare beneficiaries.

We understand the philosophy behind the intent of the Congress to pay equally for the same imaging service, regardless of the site of its delivery. However, the policy included in the DRA arbitrarily replaces the long established and validated Medicare Physician Fee Schedule payment system, with the non-validated Hospital Outpatient Prospective Payment System (HOPPS) for the Technical Component reimbursement.

The Balanced Budget Act of 1997 (P.L. No. 105-33) called for the Secretary of HHS to develop the HOPPS methodology for hospital outpatient services. Outpatient services typically are performed at a hospital and include routine visits, emergency room visits, diagnostic medical imaging services, and surgical procedures not performed as part of an inpatient stay. The hospital outpatient payment system was never designed to accurately reimburse physician practice expense outside of the hospital setting and its applicability to the cost structure of non-hospital sites of service, such as a physician office or an imaging center, has never been examined. Moreover, HOPPS fails to adequately account for the capital-intensive nature of diagnostic medical imaging services provided for in an office setting, where there is often less volume of services.

Unlike the Resource Based Relative Value System (RBRVS), which a prior Congress required to be based on specific procedure level resource costs in determination of reimbursement, the HOPPS was never intended to accurately reflect resource costs at the procedure level. The HOPPS classification methodology is a hospital case mixed index not intended to be a procedure level payment. This new Congressional proposed reimbursement scheme effectively removes physician input and the resource basis from the reimbursement system and negates the careful and rigorous work performed by the AMA Practice Expense Advisory Committee (PEAC) over the past six years.

The convoluted methodology of the HOPPS, which has relatively minor physician input into the process, is ultimately based on what hospitals report as their 'costs' for the various outpatient procedures. This reporting system is notoriously inaccurate and is not systematically validated. Before Congress discards the MPFS methodology in favor of the HOPPS methodology it should be sure that the hospitals are showing all of their costs for outpatient imaging services, especially CT and MRI as some of these costs may be allocated to the Part A Medicare payments (DRGs).

Rather than blindly believing that the MPFS over reimburses CT and MRI procedures performed in an office setting, you should have considered the more likely probability that hospitals are not showing all of their costs and, as such, that hospitals are under reimbursed.

For example, much of the cost of providing these state of the art imaging services is in the cost of the equipment. The HOPPS methodology has no specific mechanism for capturing those costs and it is quite possible that hospitals are not reflecting equipment purchase costs in their reporting system. Implementation of the legislation transitioning the HOPPS payments to the Medicare Physician Fee Schedule ***must be delayed*** until this answer is known. Otherwise, Congress may unwittingly put many imaging centers out of business because it never bothered to understand that the new reimbursement level may not even cover the costs of providing many imaging services. Simply stated, the HOPPS system was never designed to account for the costs of in-office imaging and therefore cannot be expected to be an accurate measure of the costs associated with in-office imaging.

Furthermore, the imaging cuts in the bill represent nearly a third of overall reductions in the Medicare program that were contained in the DRA and do not address the utilization concerns of many in Congress. When taken in tandem with ongoing CMS rulemaking reductions such as CMS's November 2005 final rule on contiguous body parts and CMS's June 2006 proposed rule that discusses the 5 year review and revisions to the practice expense methodology, the combination of these policies cross the threshold of defensible public policy and become arbitrary and punitive reimbursement reductions. If these cuts are implemented in January 2007, many physicians may be forced to stop offering much needed imaging services or limit the number of Medicare patients they receive. It is possible that many rural areas of the country will be affected. As a result, Medicare beneficiaries may be forced to endure increased wait and travel times to receive imaging services and higher co-payments for certain studies performed in the outpatient setting.

Many ACR members, in response to this policy, have expressed their concerns that in the event these payment reductions go into effect that they will likely be forced to reduce their hours significantly, cut staff or close altogether since they cannot increase their volume by performing more examinations in order to offset these losses. In addition to the access problems that will inevitably occur, ACR is also concerned that these cuts may discourage research and development of new imaging technologies that are increasingly replacing more invasive (and more costly) techniques. I'm sure the NEMA representative testifying today can verify that many of our members are stopping orders for new equipment and/or updates for older equipment.

Alternative Policies

Mr. Chairman, we recognize that of section 5102(b) of the DRA is intended to reduce the growth and the costs of medical imaging in Medicare. However, the DRA policy does nothing to address the growth in imaging services. Therefore, ACR and our colleagues in our Coalition, believe this issue requires a more thorough analysis, and not the sledge hammer reimbursement cuts enacted early this year. The two year moratorium contained in HR 5704 should give Congress ample time to accomplish a more thoughtful analysis of the potential unintended consequences that such severe payment cuts could portend.

To address the growing concern of policy makers in the public sector as well as with private payers who have worried about the tremendous growth in usage of PET scans, CT and MRI tests, the College has advocated for the last two years that utilization can be controlled through the development of quality and safety standards. We believe that Medicare should only pay for those complex imaging tests, CT, MRI and PET, if they are performed in a safe and controlled environment. We believe that any physician,

regardless of their specialty, should meet minimum quality and training standards. We think the equipment must continue to be of the highest caliber, with continuous maintenance to monitor the numerous safety issues associated with these complex tests. Some may view this position as anti-competitive on the part of radiologists, but we view the requirement of quality and safety standards as providing the necessary assurance to patients and taxpayers alike, that these services are being carried out in the most appropriate manner. The complexity, cost, and possible radiation exposure often associated with many of these procedures require and demand special consideration of federal quality standards.

The Mammography Quality Standards Act (MQSA)

The requirement of federal quality standards already *has* governmental precedent. In 1992, Congress enacted the Mammography Quality Standards Act or MQSA. This congressionally established program sought to increase the quality of mammographic images by setting standards for the facility, technicians and physicians involved in the mammography process, thus improving breast cancer diagnosis and ultimately breast cancer survival. Since the establishment of MQSA, earlier detection of breast cancer through quality imaging has saved thousands of women's lives.

ACR believes that if Congress thought it was important to ensure quality for the x-ray procedures involved in mammography, then it is logical that Congress would want to enact similar standards for other imaging procedures that are more complex, such as CT, in which the radiation dose is 200 times that of a conventional chest film. Clearly the Centers for Medicare and Medicaid Services (CMS) has begun to move in this direction as evidenced by its October 1, 2004 transmittal number 24 which incorporated into Medicare regulation a national coverage determination for PET scans that includes facility accreditation and demonstrated physician interpreter expertise as a requirement of coverage. Specifically, the CMS languages states "The FDG-PET scan is performed in a facility that has all the accreditation necessary to operate nuclear medicine equipment. The reading of the scan should be done by an expert in nuclear medicine, radiology, neurology, or psychiatry, with experience interpreting such scans in the presence of dementia."

While MQSA is not perfect, physicians have accepted these standards. Advances in technology continue, including recent findings that the latest digital mammography may be a particularly effective test for some high risk groups of women. Most importantly, the level of care has greatly improved and our patients, your constituents, have benefited from early detection, increased survival rates and reduced death rates.

Medicare Payment Advisory Commission (MedPAC) Recommendations

In its June 2004 and March 2005 reports to Congress, MedPAC's recommendations, which are not specialty specific, call for all diagnostic imaging providers to meet quality standards for imaging equipment, non-physician staff, images produced, patient safety protocols, and increased training for physicians who bill Medicare for interpreting diagnostic imaging procedures. As suggested by MedPAC in its March 2005 report, these standards would be determined by the Secretary of Health and Human Services (HHS) in consultation with physician specialty associations and nationally recognized accreditation organizations. Therefore, those physicians that are committed to obtaining the training, education, personnel and equipment necessary to meet these standards will continue to be able to provide services to their patients. The ACR urges the subcommittee to seriously consider and follow the advice of its advisory commission.

According to data compiled for the ACR, Congressional implementation of the MedPAC recommendations, designed in part to stem the financial incentive associated with some of the growth in imaging utilization, could save the Medicare program a minimum of $4-6 billion over ten years (the analysis behind this cost savings has been

previously provided to Committee staff). Given the likelihood that Medicare spending on the highest-cost modalities may approach $100 billion over the next ten years, deterring just 5 percent of projected spending would represent a substantial savings to Medicare. We believe that if quality of care standards were adopted, Medicare beneficiaries would receive fewer duplicative studies, with more accurate and better image quality of the range of tests available.

Independent Diagnostic Testing Facilities

While much of the increase in imaging procedures is due to the growing value of imaging as an alternative to more invasive diagnostic techniques, there is continued concern about the proliferation of expensive imaging equipment outside the traditional setting of the hospital or radiology group practice. It is in these non traditional settings where uniform quality and safety standards, usually associated with hospital and radiology group practices, do not exist.

The ACR feels that CMS currently has the authority to assert quality and safety standards to all settings where complex imaging testing is done if CMS were to expand their current Independent Diagnostic Testing Facility (IDTF) program to all settings where these tests are performed. Currently each state has authority to regulate how diagnostic imaging services are performed if such services are performed in an IDTF. Some states are diligent in this overview while others are more lax.

In order to make these standards uniform for all states, the ACR feels that CMS should nationalize the IDTF standards, and insist that the provision of CT, PET or MRI exams, when performed in an office setting should meet the qualifications of, and register as an IDTF. CMS has this authority to expand the existing IDTF program and the ACR urges the Congress to seriously consider this avenue of policy making as a fairly direct way to address many of the concerns raised in this hearing.

Private Insurers

Today, third party payers across the country are looking for ways to reign in imaging costs while ensuring that there is no negative impact on the quality of patient care. To improve image quality and reduce costs, some insurers are following accreditation models similar to those proposed by MedPAC and ACR.

More and more payers recognize that accreditation programs are a key element in evaluating and maintaining the quality and safety of imaging for their patients. In recent years carriers in various markets across the country have mandated accreditation in complex imaging modalities such as MRI and CT for their providers. Until now the only national mandate was for MRI accreditation that was implemented in 2001 by Aetna. Recently, another national payer has indicated that they will require accreditation for all providers of MRI, CT, PET, Nuclear medicine, Nuclear Cardiology and Echocardiography beginning in late 2007.

A list of some insurers and states utilizing ACR Accreditation is attached to this testimony and include Aetna, Blue Cross of California, Highmark Blue Cross of Pennsylvania, Blue Cross Blue Shield of Alabama, United Health Group of Wisconsin, Cigna of Connecticut and Oxford to name a few.

Conclusion

The ACR represents those physicians who focus solely on medical imaging and have unrivaled expertise in radiological sciences, medical imaging techniques, radiation safety, radiation protection, dose delivery and image interpretation programs. We are committed to evidence based decision making in healthcare and dedicated to high quality, safe and effective patient care through all of its available resources.

I would like to reiterate my appreciation for your interest and concern that Medicare beneficiaries continue to receive the life-saving technology found in diagnostic imaging

services. We hope the subcommittee, as well as the entire Congress, will work to enact the provisions contained in HR 5704 so that we can implement an effective and sensible imaging reimbursement policy that will benefit our patients and the health care system overall.

I look forward to any questions you may have.

Thank you.

Table 1
Private Third-Party Payers with ACR Accreditation Requirements of Some Form

Private Third-Party Payers with ACR Accreditation Requirements of Some Form (as of March 1, 2004)	ACR Accreditation Program Required
Aetna US Healthcare	MRI, Mammography, OB Ultrasound
Auto Insurance Regulations in Florida	MRI
Blue Cross of CA (NIA)	MRI
Blue Cross-NEPA/FPH	MRI
Health Now New York, Inc	MRI
Highmark Blue Cross of PA	MRI (in lieu of their own program)
One Call Medical	MRI
Blue Cross/Blue Shield of Alabama	MRI, CT, PET
New York Medical Imaging, PLLC (NYMI)	MRI, Ultrasound
Oxford Health Plans	CT, PET, Nuclear Cardiology
United Healthcare of Wisconsin	Nuclear Cardiology
Cigna of CT	OB Ultrasound
Health Net of Northeast, Inc. (NIA)	OB Ultrasound
Blue Cross of PA	OB Ultrasound
Intermountain Healthcare of UT	OB Ultrasound
PHS Health Plans (NIA)	OB Ultrasound
Blue Cross of NJ	(maintain set minimum quality standards for any provider of imaging)

Table 2
State Legislatures Who Require ACR Accreditation of Some Form

State Legislatures Who Require ACR Accreditation of Some Form: (unlawful to operate without accreditation as of March 1, 2004)	**ACR Accreditation Program Required**
California	OB Ultrasound (for Prenatal Diagnosis Centers)
Massachusetts	Stereotactic Breast Biopsy
New Jersey	Radiation Oncology
New York	Radiation Oncology (must have review every 5 yrs. by approved body)
Ohio	Freestanding Radiation Oncology facilities
Connecticut	MRI
Rhode Island	MRI

States that have Accreditation/Certification Requirements/Recommendations on Local Medicare Policies

Alaska
Arizona
Arkansas
Colorado
Delaware
Hawaii
Idaho
Illinois
Iowa
Kansas
Louisiana
Maryland
Michigan
Minnesota
Mississippi
Missouri
Nebraska
Nevada
New Jersey
New Mexico
North Carolina
North Dakota
Ohio
Oklahoma
Oregon
Pennsylvania
South Carolina
South Dakota
Tennessee
Texas
Virginia
Washington
Washington, DC
West Virginia
Wisconsin
Wyoming

MR. DEAL. Thank you.

Mr. Donahue.

MR. DONAHUE. Chairman Deal, Congressman Pallone, and members of the subcommittee, my name is John Donahue, and I am the President, the Founder, and the CEO of National Imaging Associates, and I am very honored and pleased to be before this committee today.

NIA is America's largest radiology benefit management firm. Our clients include the Nation's leading managed care organizations, such as WellPoint, Aetna, and Harvard Pilgrim. We cover 17 million Americans in 36 States across this country, including 300,000 Medicare Advantage enrollees and 1.2 million commercial Medicaid lives.

I would like to address three areas for you this afternoon. First, to describe radiology benefit management; secondly, to discuss the explosive growth in imaging costs; and thirdly, to propose some solutions.

Radiology benefit management involves applying evidence-based guidelines, nationally endorsed quality and safety standards, patient education and patient advocacy to ensure that a diagnostic imaging study is clinically appropriate, is safe, and is affordable. I strongly believe that radiology benefit management is sound policy.

The qualitative consensus shows that outpatient diagnostic imaging exceeds $100 billion and is growing at a rate in excess of 20 percent. We find almost axiomatically across many regions in this Nation that high tech imaging, MRI, CT, PET, and nuclear cardiology exams, often constitute 15 percent of imaging volume, over 50 percent of imaging costs, and a full three-quarters, 75 percent of diagnostic imaging technology inflation.

What is causing this explosion in imaging inflation and utilization? Well, members of the committee, I wish there were a straight, direct simple answer to this, but as we have heard today, it is very complex and multi-variate. It is, in fact, the perfect storm of healthcare quality, safety, and economic concern where you have innovative and therapeutically helpful new technology bombarding the marketplace, and that is a very good thing. However, there is often a lack of clinical consensus and a full understanding on the part of ordering physicians on how to apply this marvelous technology. There are malpractice concerns which encourage the defensive ordering of multiple diagnostic imaging exams, there are patients who are bombarded with direct-to-consumer imaging advertisements who often present in physician's offices with strong biases as to what specific imaging exams they would like rendered. There is a proliferation of imaging capacity across this country, sometimes not driven by clinical appropriateness, but by entrepreneurial zeal, and finally, we have the vexing issue of self-referral. Our data indicates that some referring providers across this country who have access to equipment and will refer to themselves are often up to four times more likely to order an imaging procedure than those that order but don't render the same exam.

[Slide]

As the first slide depicts--I am sorry, it is both the same slide. But as the first slide depicts, the quality, the safety, and the affordability of diagnostic imaging hinges, in my belief, on three distinct areas: the evaluation, the ordering, and the delivery of imaging care, as well as the payment of imaging care. My belief is that ordering, delivery, and payment must be addressed holistically. MedPAC and the DRA have

admirably addressed some of the delivery and the payment issues through what we believe are highly justified pricing and billing solutions. My proposed solution today focuses on evaluating the ordering of imaging studies, which most predominantly drive volume and cost.

The appropriate ordering of imaging requires evidence-based support, which assures the clinical value of a given study. The most effective means to do this is through patient and physician education on the technology, coupled with convenient physician decision support to help use the technology. Our processes are based on clinical guidelines and radiology peer-to-peer delivered at the point of ordering.

Across this Nation, we are providing physicians with clinical decision support 300,000 times per month through 4-minute Web and telephonic encounters. NIA connects ordering physicians with Board-certified radiologists while the patient is still in the office. This program adds value and we believe that it works.

[Slide]

As this slide indicates, in this particular Medicare Advantage plan, a 25 percent annual growth rate was turned around to a 20 percent reduction in the first year of the program. Exploiting this to Medicare Advantage, traditional Medicare, and Medicaid indicates that this strategy could save our Nation billions of dollars in unwarranted diagnostic imaging.

In conclusion, we feel that radiology benefit management is a viable option available to Congress to address the explosive cost of high tech imaging. We feel we can facilitate the national goal of high quality care, patient safety, and affordable imaging.

We very much appreciate the opportunity to be before you, and would welcome any questions. Thank you.

[The prepared statement of John J. Donahue follows:]

PREPARED STATEMENT OF JOHN J. DONAHUE, PRESIDENT AND CHIEF EXECUTIVE OFFICER, NATIONAL IMAGING ASSOCIATES, INC.

Chairman Deal, Ranking Member Brown, and Members of the Subcommittee, my name is John Donahue, and I am pleased to appear before you today to discuss the state of medical imaging in today's healthcare marketplace. As a fellow American, I am also deeply grateful to the commitment and contributions each of you Members have made to our Nation. I am the Founder, the President, and the Chief Executive Officer of National Imaging Associates, Inc. (NIA). NIA is the nation's largest radiology benefits management firm, covering nearly 17 million people through contracts with national and regional health plans. NIA is dedicated to improving the quality of patient care through clinically appropriate and cost-effective management of diagnostic imaging such as MRIs, CT and PET scans, and nuclear cardiology services. Robert LaGalia (who is with me today), Dr. Thomas Dehn and I , originally developed this company through a partnership with Quest Diagnostics. NIA became a separate entity in 1996, and is now a wholly owned subsidiary of Magellan Health Services. Headquartered in Avon,

Connecticut, Magellan Health Services is the nation's leading specialty health care management organization.

NIA is the only radiology management organization to receive accreditation for our HIPAA privacy compliance program for all the Protected Health Information we receive in the course of our operations. NIA was also selected as an early adopter for the new URAC and JCAHO/NCQA Privacy Certification Program for Business Associates. URAC awarded NIA HIPAA Privacy Accreditation for Business Associates in August 2003. Our Web based applications were also recognized by Computer World's Smithsonian Award for Healthcare Innovation.

Radiology benefits management involves evaluating diagnostic imaging to insure that services rendered are both clinically appropriate and cost effective. NIA currently partners with the nation's leading managed care organizations in 36 states to improve the quality and cost-efficiency of diagnostic imaging testing for health plan members and physicians. NIA's clients include the nation's leading managed care organizations, including Aetna and WellPoint, many other leading Blue Cross and Blue Shield Plans and regional leaders such as Harvard Pilgrim Health Care. In the government sector, we cover over 300,000 Medicare Advantage lives and over 1,200,000 Medicaid lives in multiple states. Given the scope of our role in our nation's health care, I believe our perspective on advanced medical imaging and the management of imaging costs can be useful to the Subcommittee.

The record on diagnostic imaging as one of the fastest growing cost areas in American health care, and the growth in advanced medical imaging as a major contributor to today's exploding Medicare spending, are both well documented. By most accounts, outpatient diagnostic imaging exceeds $100 billion and is growing at a rate in excess of 20 percent. It is interesting to note that we find almost axiomatically across the country, high tech imaging (MRI, CT, PET and nuclear cardiology exams), typically account for only roughly 15 percent of imaging volume, but over 50 percent of imaging cost (driven by their high relative fees) and over almost 80 percent of the inflationary impact. Most health plans, State authorities or Center for Medicare and Medicaid Service (CMS) will report to you that diagnostic imaging represents upwards of over 15 percent of the overall health care spend in our country. While we understand the consternation with the MedPAC recommendations, the CMS Physician Fee Schedule changes for multiple procedures and nuclear medicine services, and the imaging provisions in the Deficit Reduction Act of 2005 (DRA), we fully endorse the concept of clinically based, safe and affordable imaging as sound public policy, and we are encouraged that the Subcommittee has held this hearing today.

I am often asked: What is causing this explosion in diagnostic imaging utilization, safety concern and financial stress on our health care system? There is no single simple answer. We are here today because a compendium of causal factors are forming *The Perfect Storm*, these dynamics include:

- The constant flow of remarkably innovative and therapeutically helpful new imaging technology that is flooding the market place. To the extent this helps patients, it is very positive.
- A lack of clinical consensus on the part of those who predominantly order diagnostic imaging. Well-intentioned primary care, family practice and internal medicine physicians, who endeavor to perform the best care for their patients but lack the time and acumen to master the nuances of every emerging technology, most often cast a wide, extraordinary costly and most often not clinically justified net of imaging prescriptions.
- There is a reflexive professional instinct to cast a broad net of multiple diagnostic imaging exams to protect a doctor from financially devastating and often unjustified instances of physician malpractice.

- And then there is the patient, who is bombarded with direct-to-consumer imaging advertisement, an enlightened sense of technological awareness, mixed with a smidgen of entitlement. He often requests specific imaging exams when thinking, "I twisted my knee this weekend playing hoops in the driveway, I want an MRI on a GE magnet just like my local sports star had last week."

Now, we turn to two of the most concerning issues this Committee will face:

- There is a proliferation of imaging capacity driven by entrepreneurial zeal and resulting in imaging orders, which is encouraged by aggressive marketing. They are not clinically warranted and are driven by return in investment decisions by the owner.
- World of self referral: We must find a solution to this gaping hole in the Stark legislation. A solution is necessary which affords patients access to highly skilled and convenient non-radiologist imaging care, while protecting our health care system from unsavory financially driven imaging utilization.

I have a solution for you to consider for both of these points. I will describe how diagnostic imaging is delivered in America. At NIA we organize this into three distinct areas: (1) ordering of imaging care; (2) delivery of imaging care; and (3) payment of imaging care.

Ordering, Delivery and Payment are the most quintessential elements of any capitalistic system whether it is widgets, or automobiles or diagnostic imaging. Scarcely anywhere is there more need in America for more governmental guidance on safety, clinical assurance and financial appropriateness than in the area of diagnostic imaging. It is also my firm belief that ordering, delivery and payment of imaging must be addressed holistically to achieve the goals of improved clinical care, patient safety and financial affordability. MedPAC and the DRA legislation have admirably addressed some of the delivery and payment issues – through highly justified pricing and billing solutions.

However, ordering of imaging tests, which predominantly drives volume and cost more than any factor has been, respectfully, somewhat under addressed. Let me zero in for a moment on the ordering of imaging care. Remember, while self-referral is a justifiable concern, the vast majority of imaging exams in this country are ordered by physicians who will not render or economically benefit from their generation. As mentioned previously, these are the physicians who are, in every state in this nation, bombarded with a flow of innovative but confusing and costly new technology or applications of existing technology, patient demand and an uneasy concern over applying justifiable conservative ordering in the face of rampant malpractice litigation.

The appropriate ordering of imaging care requires evidence based support which tests clinical value. We find the most effective means to do this is through patient and physician education coupled with convenient physician decision support (founded in evidenced based medicine) at the point of ordering. Across this nation, we are providing physicians with clinically invaluable decision support (300,000 times per month) through 4 minute web and telephonic interaction and connection with board certified radiologists, while the patient is in the office. This service enlightens physicians, protects patients from clinically unwarranted and unsafe procedures and saves our managed care partners hundreds of millions of dollars per year by eliminating wasteful imaging exams. I strongly encourage this subcommittee to examine this methodology because we think it provides a solution transferable to the public health insurance programs. As you will hear, we feel this enlightened approach can unlock tens of billions in clinically warranted economic savings for our country.

NIA is confident that the empirical data demonstrates that clinically appropriate radiology benefits management is the responsible approach that offers the necessary cost reductions while ensuring the safety of the patients who require treatment. Our

experience in radiology management has led us to three conclusions that I want to share with you. Congress should not shy away from a robust dialogue on the issue because:

1. Roughly One-Third of Advanced Imaging Tests Are Inappropriate or Do Not Contribute to Health Outcomes. We have first-hand experiences and successes managing imaging benefits for Medicare Advantage plans. We have found about one-third of advanced imaging tests are either inappropriate or do not contribute to the physician's diagnosis or ultimate health outcomes. For example, such tests could possibly be performed more efficiently and economically, and achieve the same clinical/diagnostic goal, with traditional technology. Applied to the nation as a whole, this data strongly suggests that efficient radiology benefit management could cut America's radiology expenditures by $20 billion to $30 billion annually.

2. There Are Inherent Risks In Radiation Exposure. There is no question that patient care is vastly improved when diagnostic imaging services are performed, but the inherent risks associated with radiation exposure should not be trivialized. The medical consequences that result when patients incur too much exposure to radiation may not be apparent to a physician when identifying what is in the best interest of the patient. This has the potential of trying to solve a problem by creating a brand new health risk to the patient.

3. There is a Substantial Incidence of Self-Referral for Nuclear Medicine Services. In our experience, self-referral is a driver of escalating imaging costs, despite nuclear medicine's approval as designated health service under the Stark Act. Since imaging services can be performed in referring physicians' offices under an exception, growth in self-referrals will undoubtedly continue to proliferate with little or no exceptions, despite the change in CMS rules. Our data shows that 68 percent of the encounters of nuclear cardiologists who made referrals for nuclear cardiology services within a major health plan in 2003 were self-referrals. When the data is stratified another way, virtually all providers whose self-referral rates were classified as "high" were nuclear cardiology referrals (1,045 out of 1,050). This practice must stop.

Taken together, the findings outlined above, and discussed in more detail below, suggest that the fiscal integrity of Medicare and Medicaid as well as the health and safety of beneficiaries are at risk with the explosive growth in imaging spending. We endorse the concept of cost controls and radiology benefits management and can demonstrate clinically appropriate and safe imaging management.

1. Roughly One-Third of Advanced Imaging Tests Are Inappropriate or Do Not Contribute to Health Outcomes.

In our experience, about one third of advanced imaging tests are either inappropriate or do not contribute to the physician's diagnosis or ultimate health outcomes. We maintain the nation's largest clinical and financial database that includes over 150 million imaging encounters. Among a variety of uses, the data enables us to provide the industry's most advanced algorithms to enhance the quality and efficiency of radiology modality choices, while providing doctors and plan partners with important information on radiology ordering practices.

NIA has drawn on its clinical and financial database from a sampling of pre-authorizations submitted through major managed care organizations for the period of September 1, 2004 through August 31, 2005. The data from our sample show that almost one-third of all requests for imaging services involved multiple procedures using the same modality for related body parts during a single clinical session. Specifically, there were more than 330,000 requests in our sample, and, of these, nearly 110,000 involved multiple procedures. In all, the data in our sample show a substantial incidence of requests for multiple procedures in a single session.

In another instance, NIA turned nearly 25 percent annual growth in Medicare Advantage imaging claims into a reduction of nearly 20 percent in the first year. This

swing of nearly 45 percent exceeded NIA's management of the plan's commercial imaging benefit. Furthermore, this reduction helped the plan realize a savings of nearly $6.50 in its per-member per-month Medicare Advantage imaging rate, four times the per-member per-month savings realized on the non-Medicare side.

2. There Are Inherent Risks In Radiation Exposure.

As important as responsible cost management is, patient safety always comes first. We strive to help good doctors become better doctors. While patient care is vastly improved when diagnostic imaging services are performed, there are inherent risks associated with radiation exposure that should not be trivialized. We live in a society where an abundance of caution often supersedes what is an appropriate course of action. A doctor's assessment of the appropriateness of radiation exposure to a patient requires a subjective evaluation of the potential benefit to the patient in relation to the additional radiation risk resulting from the imaging test.

The medical consequences that result when patients incur too much exposure to radiation may not be top-of-mind for a physician when identifying what is in the best interest of the patient, which has the potential to cause a brand new health risk. For example, a July 2005 National Academy of Sciences report underscored the fact that ***any*** level of ionizing radiation may have carcinogenic effects[1]. NIA strives to mitigate overexposure to radiation by tracking patient dosages, through a combination of recent claim and pre-authorization data, and, through management techniques, preventing unnecessary and harmful exposure to clinically unnecessary and potentially dangerous radiation.

Radiology benefits management can reduce the dangers caused by too much radiation from too many procedures. We work with our clients to focus on patient exposure to radiation and the need to balance the risks and benefits of those procedures through utilization management.

3. There is a Substantial Incidence of Self-Referral for Nuclear Medicine Services.

Another driver of the cost boom is the ever-growing entrepreneurial physician network, comprised of doctors who have purchased imaging equipment and have a desire to see a return on their investment. Self-referral practices are emerging everywhere. Specialty and primary care practices are buying their own CT and MRI scanners, entering special lease agreements, and self-referring their patients while outsourcing the radiologists' interpretations. A May 3, 2005 article in the *Wall Street Journal* examined "increasingly common" arrangements in which physicians contract with medical imaging centers to "structure referral deals as leases, under which physicians, each time they send over a patient, are renting the scan center's facilities and employees." Under the arrangements, the medical imaging centers charge physicians a flat rate per scan and physicians can bill health insurers for the scans at the reimbursement rate in their area.

Information drawn from NIA's clinical and financial database supports the view that there is substantial incidence of self-referral for nuclear medicine services and that self-referring providers are much more likely to order these types of services than those who do not self-refer and they do so with no concomitant clinical justification. Specifically, we reviewed data on nearly 1,000 providers who made referrals for nuclear cardiology services within a major health plan in the period June 2002 through May 2003. In all, 1,605 referrals for these services were recorded, of which 1,096 – 68 percent – were self-referrals.

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[1] National Academy of Science Health Risks from Exposure to Low Levels of Ionizing Radiation: BEIR VII Phase 2 Committee to Assess Health Risks from Exposure to Low Levels of Ionizing Radiation, National Research Council 2005

We also stratified our data to identify groups of providers whose self-referral rates were classified as "high," "medium," and "low." In the "high" group of providers, virtually all nuclear cardiology referrals – 1,045 out of 1,500 – were self-referrals, while in the "low" group virtually none of the referrals were self-referrals. Using these classifications, we were able to determine that self-referring providers in the "high" group were four times more likely to make a nuclear cardiology referral *of any kind* than were providers in the "low" group.

It is clear that self-referring is a culprit for climbing imaging costs, despite nuclear medicine's approval as a designated health service under the Stark Act. Since imaging services can be performed in referring physicians' offices under an exception, growth in self-referrals will undoubtedly continue to proliferate with little or no exceptions, despite the change in CMS rules. This practice must stop. Self-referral is manipulating a loophole that must be closed in order to establish parity and allow the true intent of the Stark Act to properly police the imaging community.

CONCLUSION: A PROPOSED SOLUTION FOR MOVING FORWARD: PRIOR AUTHORIZATION AS A CHECK FOR IMAGING COSTS

NIA's safeguards ensure that patients receive clinically appropriate and safe imaging in an efficient and timely manner, but we recognize that pre-authorization programs are not always embraced by physicians. Therefore, we endeavor to expedite the pre-authorization process. Within minutes, referring physicians or their clinical staffs receive approval or are notified that the decision has been forwarded for clinical consultation by a Board-Certified Radiologist or physician. The best radiology professionals in medicine, including our over 60 board-certified radiologists and other specialists handle those cases that require further judgment on a peer-to-peer consultative basis. If a request is denied on a clinical basis, our reviewers always recommend an appropriate alternative procedure. No request is ever denied without a concerted effort by our physicians to discuss the matter with the referring physician in peer-to-peer dialogue.

Out safeguards ensure that patients receive clinically appropriate and safe imaging in an efficient and timely manner, but we recognize that pre-authorization programs are not always embraced by physicians. We endeavor to expedite the process. Within minutes, referring physicians or their clinical staff receive approval or are notified that the decision has been forwarded for clinical consultation by a board-certified radiologist or physician. Expert physicians, including over 60 board-certified radiologists and other specialists, handle those cases that require further judgment on a peer-2-peer consultative basis. If a request is denied on a clinical basis, our reviewers almost always recommend an appropriate alternative procedure. No request is ever denied without a concerted effort by our physicians to discuss the matter with the referring physician in peer-2-peer dialogue.

NIA also publishes up-to-date clinical guidelines covering the common reasons for requesting imaging tests. These guidelines have been developed from practice experience, literature reviews, specialty criteria sets, and empirical data from credible medical organizations such as the American College of Radiology, the American College of Cardiology, and other specialty doctor groups. Our proprietary algorithms are developed and updated using NIA's imaging database with reference to the latest medical literature. The algorithms are regularly reviewed and approved by state Imaging Advisory Committees, health plan Chief Medical Officers, state medical societies, and updated by our database of encounters which grows by 300,000 calls per month.

We believe that there are a number of options available to both Congress and the Administration as a means of identifying and deploying cost-cutting initiatives in imaging.

Congress could enact two of the 2005 MedPAC recommendations which require federal standards for physicians who perform diagnostic imaging procedures, as well as for those physicians who read and interpret the images. While the establishment of federal standards for medicine is admittedly a difficult and complex procedure, there is a precedent for setting these standards. For example, the Mammography Quality Standards Act (MQSA) that was first enacted in 1992 and reauthorized three times since could justify a legislative effort to set federal standards for other forms of diagnostic imaging. Furthermore, another law that demonstrates that the federal government does have a role, and responsibility, to set medical standards is the Clinical Laboratory Improvement Amendments (CLIA), which was enacted by Congress nearly 20 years ago in 1988. Just as MQSA established standards for mammography facility, CLIA did the same for laboratory testing.

We believe that these two laws illustrate a federal precedent for establishing medical standards and regulating the practice of medicine. Patient safety was the genesis behind both MQSA and CLIA, and we believe that the same argument can be applied more broadly across the spectrum of diagnostic imaging procedures. Clearly, patient safety is an issue in diagnostic imaging, e.g. exposure to excessive radiation, the improper handling of a patient, and the accuracy and reliability of tests.

Second, we believe that there are opportunities with Congress and CMS for the development of creative new techniques in the management of radiology services. For example, radiology benefits management could be a key enabler of "pay for performance" and other value-based purchasing systems planned for Medicaid, Medicare Advantage, and fee-for-service Medicare. We have had some discussions with CMS officials on this topic, and we welcome any opportunity to broaden our dialogue on this issue. There is the potential of advancing this issue under a pay-for-performance proposal where payments to imaging providers are linked to quality and efficiency, which would address the issue of exploding costs. We look forward to the opportunity to collaborate with Congress, the Administration, and other stakeholders to develop an appropriate pilot program that strikes a balance between cost savings and patient safety. NIA recognizes that these are lofty goals being suggested at a time when the Congressional calendar is winding down. But, sound public policy initiatives require visionaries and forward thinkers, and the time is now to consider the framework for a pragmatic healthcare agenda for the 110th Congress and beyond.

Thank you for the opportunity to appear before you today. I would be delighted to answer any questions you may have.

MR. DEAL. Thank you.

Dr. Laube.

DR. LAUBE. Thank you, Chairman Deal, for the opportunity to discuss the use of ultrasound in our specialty, and its importance to the women we serve.

I represent the American College of Obstetricians and Gynecologists, a membership organization of over 50,000 obstetricians and gynecologists.

The safety and longstanding integration of ultrasound in medical offices sets it apart from other parts of imaging, including CT, MRI, and PET. Congress should recognize these differences and exempt OB/GYN ultrasound from many of the proposals under consideration.

To make my point, I will summarize the major points in the written testimony, which are five.

First, ultrasound is safe. Ultrasound uses low-intensity sound waves to generate images, not ionizing radiation or potential carcinogen in X-ray, CT, and nuclear medicine. No harmful effects have ever been associated with the medical use of ultrasound. The clinical benefits far outweigh any potential risk.

Second, OB/GYN residents are extensively trained in ultrasound throughout their f4 years of training. Since 1982, ultrasound has been recognized as an essential element of OB/GYN training. As someone who has been in academic medicine for 25 years and has trained over 350 OB/GYN residents, I can certainly attest to the integration of ultrasound in our medical training. ACOG offers postgraduate medical education in ultrasound and educates its fellows on appropriate use. ACOG has worked with the American Institute of Ultrasound Medicine and with the American College of Radiology to develop clinical practice guidelines and a voluntary accreditation program.

Third, ultrasound use in physician offices saves healthcare costs and improves quality of care. Use of ultrasound in clinical care speeds decision-making and enables greater reliance on minimally invasive, less costly procedures. Many exams need to be performed urgently, such as when women experience unexplained bleeding, pelvic pain, or discovery of a mass. Ectopic pregnancies or complications during active labor can be life-threatening, and require immediate ultrasoundography. Ultrasound has greatly reduced the need for exploratory surgery.

Fourth, ultrasound is growing at a much slower rate than other imaging services. For ultrasound codes billed by OB/GYNs for the diagnosis of gynecologic conditions, the growth between 2001 and 2003 was less than 4 percent a year. This growth rate is entirely appropriate and reflects in part a shift in services from costly hospital settings to less costly office settings. Any assessment of Part B growth in ultrasound use needs to take into account the companion reduction in hospital ultrasound. Office based imaging allows patients to have the same exam or procedure in the office that they would have had previously in the hospital. It is more convenient for the patient and allows for faster diagnosis and treatment.

In addition, our patients are aging. More people are living longer with chronic disease, and pregnancy rates are soaring among women older than 35. These women are more likely to have pregnancy complications and are at increased risk for birth defects. Ultrasound is indicated for these reasons, and many older mothers should expect ultrasounds and ultrasound-guided tests, such as amniocentesis or corionic filler sampling.

In a high-risk specialty like mine, some imaging growth is undoubtedly due to defensive medicine, and until Congress acts to solve

America's medical liability crisis, the cost of defensive medicine, including imaging, will grow.

Fifth and last, current imaging proposals are not necessary for ultrasound. Accreditation measures are unnecessary for OB/GYNs who are trained in ultrasound from the beginning of their residency and are certified by the American Board of OB/GYN in its use. Many OB/GYNs are in small practices. Unlike multi-million dollar practices using CT and MRI equipment, or for freestanding imaging centers, a solo practitioner doesn't have the office support to manage the process of accreditation. In the end, no Federal certification or accreditation standards can guarantee that the right diagnostic test is provided in the right setting at the right time. This can only be accomplished through the training programs and education as those that we offer through ACOG.

In summary, ultrasound has undeniable benefits for both patients and physicians needing speedy diagnosis and timely treatment. It has a long record of safe use it used appropriately in clinical settings. Growth is low and appropriate. We urge Congress to recognize the value and distinctions of ultrasound as it considers various imaging proposals. Thank you.

[The prepared statement of Dr. Doug Laube follows:]

PREPARED STATEMENT OF DR. DOUG LAUBE, PRESIDENT, AMERICAN COLLEGE OF OBSTETRICIANS AND GYNECOLOGISTS

On behalf of the American College of Obstetricians and Gynecologists (ACOG) and our 51,000 physicians and partners in women's health, I would like to thank Chairman Deal and members of the Energy and Commerce Health Subcommittee for the opportunity to discuss the use of ultrasound in our specialty and the importance of this technology to the women we serve. I am the Chair of the Department of Obstetrics and Gynecology at the University of Wisconsin and the current President of the American College of Obstetricians and Gynecologists.

I would like to focus on the imaging most used in my specialty—ultrasound. We believe the safety and longstanding integration of ultrasound in medical offices sets it apart from other forms of imaging and warrants special consideration in this debate.

Medicare patients make up only 13% of the average ob-gyn practice. This small but significant percentage includes both older women and women with disabilities of all ages. While today's hearing is focused on imaging in Medicare, the decisions about Medicare policy this Committee may make will be adopted widely by private payers, Medicaid and TRICARE, the health care system for 9 million military families. Clearly, women of all ages throughout the country stand to be affected by these decisions.

Medical imaging is a complex subject. Discussions of growth and safety of imaging must clearly distinguish between different types of imaging. Setting it apart from other imaging, ob-gyn ultrasound has a high record of safety, is fully integrated in day-to-day patient care, and is a critical part of medical resident education. A distinction between ultrasound and the rest of the imaging field, including CT, MRI, and PET, is warranted. **We urge the Congress, in any legislation, to recognize the safety, quality and appropriateness of ultrasound studies and to exempt ultrasound from any new**

restrictions on imaging use, federal quality standards, or additional administrative burdens.

Unique Characteristics of Ultrasound

Ultrasound uses low intensity sound waves to generate images. Most people are familiar with obstetric ultrasound as a way to evaluate the health of a fetus in utero. But ultrasound has broader application and value in obstetrics and gynecology and across several medical specialties. In obstetrics, ultrasound is useful in helping to accurately date a pregnancy, estimating the amount of amniotic fluid and detecting birth defects. Ultrasound may be necessary if there is a complication during labor or to identify an ectopic pregnancy, a life-threatening condition. In gynecology, ultrasound is used to identify the cause of unexplained pain or bleeding, to visualize a mass felt during a manual exam and in the assessment of infertile patients.

Ultrasound has been established as an accurate imaging modality for many conditions. Other specialties use sonography to identify cysts or tumors in the breast, look for causes of abdominal pain, investigate causes of joint pain, or identify an enlarged prostate. In some conditions requiring a biopsy, ultrasound can be used to guide needle placement and eliminate the need for surgery. Ultrasound is also used to guide the needle placement during amniocentesis to reduce the risk of maternal or fetal injury.

Ultrasound has many advantages over other types of imaging. Since it does not use ionizing radiation or contrast media, to which some patients are allergic, it is much safer. Transabdominal ultrasound does not require sedation and is performed non-invasively, reducing risk of infection and other potential adverse events. Portable or hand-carried equipment allows scans to be performed in an ob-gyn's exam room to capture real-time images, including fetal movement and umbilical blood flow. Critical clinical data are immediately available to the physician making patient care decisions. Its convenience for physicians and patients, and real-time precision have made ultrasonography an essential tool for early diagnosis of disease and quality health care.

Ultrasound is an essential part of ob-gyns' clinical care. With several decades of clinical use, ultrasound is fully integrated into patient care. Removing this tool from the exam room or creating burdensome new requirements for physicians who use it will only bring harm to patients who want and need timely diagnosis and accurate information. Congress should reject proposals to restrict the use of this tool.

Ultrasound is different from other imaging services for several reasons:

- Ultrasound is safe;
- Training is incorporated into residency and board exams for many physician specialties and all ob-gyns;
- Use of ultrasound saves money and improves quality; and
- Growth of ultrasound is appropriate and is no faster than growth in other Medicare Part B services.

These many important differences lead us to the conclusion that proposals in the imaging debate are unnecessary for ultrasound.

Ultrasound is Safe

The first consideration in the use of any technology should be its safety. Diagnostic ultrasound uses low intensity sound waves to generate images, unlike x-ray, CT and nuclear medicine, which require ionizing radiation, a potential carcinogen. Additionally, ultrasound does not require the use of contrast media, which are required for angiography and some CT studies, and cause adverse events in a significant number of patients.

After many years of widespread clinical use, the FDA (among others) has found no known harmful effects associated with the medical use of ultrasound[1]. Studies in humans have revealed no direct link between the use of diagnostic ultrasound and any adverse outcome. It is the general consensus that the clinical benefits of ultrasound far outweigh any potential risk.

In particular, ACOG has carefully investigated the safety of scanning during pregnancy. In this regard, we concur with the FDA statement that "ultrasonic fetal scanning is generally considered safe and is properly used when medical information on a pregnancy is needed. But ultrasound energy delivered to the fetus cannot be regarded as completely innocuous. Laboratory studies have shown that diagnostic levels of ultrasound can produce physical effects in tissue, such as mechanical vibrations and rise in temperature. Although there is no evidence that these physical effects can harm the fetus, public health experts, clinicians, and industry agree that casual exposure to ultrasound, especially during pregnancy, should be avoided. Viewed in this light, exposing the fetus to ultrasound with no anticipation of medical benefit is not justified."[2]

ACOG has taken a firm position against the non-medical use of ultrasound and is alarmed by the emergence of imaging centers whose sole use of ultrasound is for entertainment, or 'keepsake' ultrasound, a practice that ACOG does not endorse.[3] ACOG has advised several imaging centers of our position and at ACOG's urging some imaging manufacturers have adopted similar positions.

Ob-Gyns are Well-Trained and Well-Qualified to Perform Ultrasound Exams

Taking ultrasound out of the ob-gyn office is akin to taking away the stethoscope, it is so integrated with the care ob-gyns provide, particularly in the treatment of pregnant women. Procedures performed by ob-gyns include sonography to assist in the diagnosis of certain pregnancy complications, diagnosis and management of certain gynecological cancers, sources of pelvic pain or postmenopausal bleeding. Maternal-fetal medicine specialists, who work with high-risk pregnant women, are trained in the use of fetal echocardiography to investigate fetal heart problems. Patients requiring advanced imaging procedures--such as MRI, CT and PET--are generally referred to a radiologist.

Residency Education

Since 1982, ultrasound has been recognized as an essential element of ob-gyn training. Training in ultrasound begins early in residency and continues throughout. The manual for the American Residency Coordinators in Obstetrics and Gynecology (ARCOG) specifies that by the end of the first year of training, ob-gyn residents must learn ultrasound physics and be able to perform time scanning and interpretation under supervision. By the end of the second year, ob-gyn residents observe and perform advanced ultrasound procedures under supervision and can interpret sonograms. In the third year, residents are expected to be able to identify normal anatomy on transvaginal ultrasound, as well.

In addition, the Accreditation Council for Graduate Medical Education ob-gyn residency requirements explicitly state that educational curriculum must include obstetric

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[1] U.S. Department of Health and Human Services, Public Health Service, Food and Drug Administration: An Overview of Ultrasound: Theory, Measurement, Medical Applications, and Biological Effects. Publication # FDA 82-8190

[2] U.S. Food and Drug Administration, Center for Devices and Radiological Health, Diagnostic Devices Branch. Fetal Keepsake Videos. Available at: http://www.fda.gov/cdrh/consumer/fetalvideos.html.

[3] ACOG Practice Bulletin No. 58, Ultrasound in Pregnancy; ACOG Committee Opinion No. 299, Guidelines for Diagnostic Imaging During Pregnancy; ACOG Committee Opinion No. 297, Nonmedical Use of Obstetric Ultrasound; American Institute of Ultrasound in Medicine. 1999. Prudent Use; American Medical Association, H480-955: "Keepsake" Fetal Ultrasonography.

and gynecologic ultrasonography and other imaging techniques. Under guidelines from the Council on Resident Education in Obstetrics and Gynecology (CREOG), graduating ob-gyn residents must be able to understand and independently perform diagnostic ultrasonography. The American Board of Obstetrics and Gynecology tests extensively on this subject in certification and recertification exams.

Obstetric ultrasound has been in ob-gyn offices for so long that radiology residents see very little of it in their training. One study found that radiology residency programs provided fewer than 4 weeks per year of obstetric sonography and that radiology residency and fellowship lecture topics were similarly deficient. The authors concluded that for radiology residents "current levels of experience in obstetric sonography may not be providing sufficient experience to allow residents to appropriately manage call cases or for practicing radiologists to provide such services after their training is completed."[4]

The Role of Specialty Societies in Ensuring Quality

ACOG, and other specialty societies, offer many opportunities for postgraduate medical education in ultrasound through seminars and meetings. In addition, several specialties have developed guidelines for appropriate use of imaging technology. ACOG has several publications to educate Fellows on appropriate usage of this technology. Practice Bulletins offer guidance on choosing a transducer; differentiation between standard, limited and specialized examinations; the indications and parameters for first, second and third trimester ultrasound; and proper documentation of the scan. These criteria were published in the journal *Obstetrics and Gynecology* and are widely available to our members. In addition, ACOG has worked with the American Institute of Ultrasound in Medicine (AIUM) and with the American College of Radiology (ACR) to develop clinical practice guidelines for antepartum obstetrical, female pelvic and saline infusion sonohysterography and voluntary accreditation programs.

When specialty societies see the need for further education, training can be developed to fill the gap. To facilitate the incorporation of ultrasound into surgical practice, the American College of Surgeons developed an ultrasound education program consisting of didactic and hands-on learning.[5] It consists of a basic, core module that covers ultrasound physics, instrumentation and scanning technique, and clinical applications. The basic core module is a prerequisite for education in the advanced training modules. There are advanced training modules in acute or trauma, vascular, abdominal, anorectal, head and neck, and breast ultrasound. Questions are included on the American Board of Surgery qualifying and in-service examinations that require the interpretation of ultrasound images.

Use of Ultrasound Saves Money and Enhances the Quality and Safety of Care

Use of ultrasound in clinical care speeds decision-making and enables greater reliance on minimally invasive, less costly, procedures. Many exams need to be performed urgently, such as when a woman experiences unexplained bleeding, pelvic pain or discovery of a mass. Ectopic pregnancies or complications during active labor can be life threatening and require immediate ultrasonography so the patient can be cared for quickly. Ob-gyns are the most appropriate physicians to provide these services. Radiologists often are not on call throughout the night and on weekends when many

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[4] CJ Kasales et al. Training in Obstetric Sonography for Radiology Residents and Fellows in the United States. American Journal of Roentgenology. 2001; 177: 763-767.

[5] ED Staren, MM Knudson, GS Rozycki, JK Harness, DC Wherry, SR Shackford. An evaluation of the American College of Surgeons' ultrasound education program. American Journal of Surgery. 2006. 191(4):489-96.

emergencies occur. It is critical that women have access to diagnosis and treatment when they need it.

In ob-gyn, as in many other specialties, ultrasound has greatly reduced the need for "exploratory" surgery or invasive diagnostics to make the same determination. In many cases, integration of ultrasound can have considerable cost savings, in addition to quality of care and patient benefits.

- Continuous ultrasound guidance improves the safety of third trimester amniocentesis and reduces costly complications. In one study, ultrasound guidance helped achieve a 99% success rate, considerably higher than the 87% success of the procedure in previous studies without using ultrasound guidance.[6] Prior to ultrasound guidance, complications were common and often serious, including premature rupture of membranes, infection, maternal hemorrhage, fetal or placental hemorrhage, fetal distress and fetal injuries.
- Ultrasound imaging in clinical practice enables a breast surgeon to perform a minimally invasive breast biopsy and determine whether the lump is cancerous in a matter of days. Previously a surgeon had to do an open biopsy and the patient waited as long as 10 days to learn the result. The Medicare program is estimated to have saved as much as $88 million because of the use of image-guided breast biopsies instead of open biopsies between 2001 and 2003.[7]
- One study found that use of transvaginal ultrasound as the initial diagnostic test to evaluate peri- and post-menopausal women with abnormal vaginal bleeding has been found to yield substantial cost-savings over biopsy-based treatments. Endometrial biopsy is a relatively inexpensive test for identifying endometrial cancer but is a poor test for diagnosing benign endometrial abnormalities. Transvaginal ultrasound is more sensitive to these benign conditions and may be a cost-saving, less invasive alternative to biopsy.[8]

In other examples:

- Ultrasound guidance of central venous catheterization (CVC) placement reduces the risk of devastating complications by 75%.
- Point of care evaluation of torso trauma resulted in decreased mortality and reduced inpatient length of stay. A conservative estimate of the resulting savings is $569 million per 100,000 patients.[9]
- A study examining endoscopic ultrasound with fine needle aspiration for preoperative staging of esophageal cancer resulted in potential cost reductions of $12,340 per patient by reducing the total number of thoracotomies performed.[10]
- Point of care, limited ultrasound during evaluation of patients for cardiac conditions revealed sufficient information for clinical decision making in 80% of cases. The remaining 20% received a detailed cardiac ultrasound. Using this staged approach, total costs were reduced by 33% and time to diagnosis was reduced from four days to instantaneous.[11]

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[6] MC Gordon, K Narula, R O'Shaughnessy, W Barth. Complications of Third-Trimester Amniocentesis Using Continuous Ultrasound Guidance. Obstetrics and Gynecology. 1999. 99 (2). 255-259.

[7] An Analysis of the Use of Ultrasound Imaging Services in the Medicare Program, The Lewin Group, May 27, 2005

[8] Medverd JR, Dubinsky TJ. Cost analysis model: US versus endometrial biopsy in evaluation of peri- and postmenopausal abnormal vaginal bleeding. Radiology 2002;222(3):619-27.

[9] Effect of Early Ultrasound on Outcomes of Trauma Patients, Acad Emerg Med 2000, 7:501

[10] Impact of endoscopic ultrasound combined with fine-needle aspiration biopsy in the management of esophageal cancer, Endoscopy. 2003 Nov;35(11):962-6.

[11] Clinical utility and cost effectiveness of a personal ultrasound imager for cardiac evaluation during consultation rounds in patients with suspected cardiac disease, Heart. 2003 Jul;89(7):727-30.

- Thyroid nodules are a common occurrence. The usual approach to diagnosing these nodules is fine needle aspiration biopsy. When ultrasound guidance is used for these biopsies, the success rate of the procedure jumps from 75% to 94% avoiding a costly hospital-based open biopsy.[12] The cost of using ultrasound each time – roughly $150 – compared with the cost of an open biopsy – approximately $2900 – shows that using ultrasound routinely in these cases could save $40,000 per 100 patients.
- A 2003 study by the UK's National Institute for Clinical Excellence and published in *The British Medical Journal* found that patients experience fewer complications when providers use ultrasound imaging to guide insertion of the catheters. Economic modeling showed that using ultrasound to place central venous catheters would save £2000 for every 1,000 procedures. This included the costs of purchasing ultrasound machines and training medical staff.[13]

Growth in Ultrasound Utilization

In its March 2005 Report to Congress. MedPAC estimated overall imaging growth to be at a rate of 10.1%, compared to a 5.2% overall growth rate in Medicare physician services between 1999 and 2002. This analysis fails to differentiate between the growth rate of ultrasound versus the growth rate of advanced imaging and does not adequately reflect savings from in-office ultrasound. Further analysis of the data show that MedPAC also may have understated overall growth in Medicare services, making imaging growth seem larger by comparison.

Ultrasound imaging in the physician office grew slower than imaging services in general (8.9% versus 10.8%). Ultrasound imaging services also grew slower than all Medicare Part B services (7.2% versus 7.8%) when looking across physician and outpatient settings. For some categories of ultrasound services, such as the ultrasound codes billed by ob-gyns for diagnosis of gynecologic conditions, the growth in this period has been less than 4% a year.

The overall Part B growth rates used in the analysis by the Lewin Group differ significantly from those reported by MedPAC in its March 2005 report to Congress (which cited a 4.3% average annual growth rate from 2001 to 2002). This difference is primarily explained by our inclusion of all Medicare services, where MedPAC compared imaging growth to only selected types of physician services. In particular, MedPAC did not include durable medical equipment, or the "Other" category in its analysis. (The "Other" category consists primarily of high-growth chemotherapeutic drugs for cancers, other drugs and biologicals covered under Medicare Part B, and ambulance services.) Additionally, our analysis is based on all Medicare Part B claims, while MedPAC used physician claims from a 5-percent random sample of Medicare beneficiaries.

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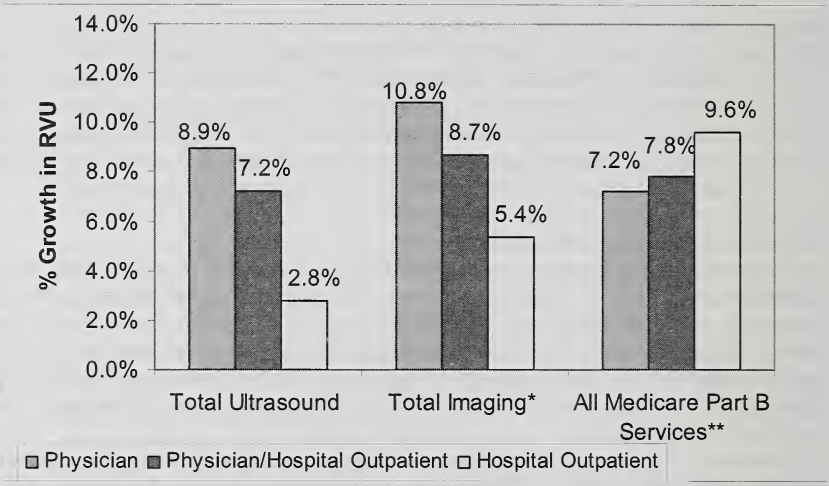
[12] Efficacy of Ultrasound-Guided Fine-Needle Aspiration Biopsy in the Diagnosis of Complex Thyroid Nodules, The Journal of Clinical Endocrinology & Metabolism, Vol 86, No. 9 4089-4091.

[13] The Effectiveness and Cost-Effectiveness of Ultrasound Locating Devices for Central Venous Access: A Systematic Review and Economic Evaluation, Calvert N, Hind D, McWilliams RG, Thomas SM, Bererley C, Davidson A; Health Technology Assessment 2003; 7 (12), National Institute for Clinical Excellence, March 2003

Table 1
Average Annual Growth in Volume of Medicare Part B Services across Providers from 1999-2003 (Based on 2005 RVUs)



Source: The Lewin Group's analysis of the Medicare Physician/Supplier Master Summary File.
* Total Ultrasound includes BETOS categories I3A–I3F
**Total Imaging includes BETOS categories I1A-I4B
*** All Medicare Part B Services includes all BETOS categories, including drugs, durable medical equipment, and ambulance services. Growth in Hospital Outpatient Services spending is estimated by using growth in allowed charges deflated by the hospital market basket. This is then weight averaged with the growth in physician services, using total allowed charges for the weights, to estimate growth in All Medical Services for Physician/Hospital Outpatient

Explaining Growth: Shift in Site of Service

Lewin found that the application of ultrasound by different specialties is appropriate to their patient populations, as well as a shift in ultrasound services from the hospital into the physician's office, which benefits patients in terms of convenience and accelerates diagnosis and treatment.

Table 1 reflects the average annual growth in physician- and hospital-billed services for the period from 1999 to 2003. The differences between the growth rate in physician-billed services and the combination of physician- and hospital-billed services indicates, in part, a shift in site of service. For ultrasound in particular, the numbers suggest services were shifting out of hospital outpatient departments towards physicians' offices. The same trend, and potential shift in site of service, is not evident in all Medicare services. Significant growth continued in all sites of service over the 1999 to 2003 time period.
As much as 19-21% of the growth in the technical component of ultrasound imaging is attributable to the shift in site of service, contributing significantly to the appearance of growth in these services. But a significant share of the perceived growth may not be growth at all, but a simple one-for-one substitution of scans that were previously performed in the hospital outpatient department and are now performed in the physician's office.

Understanding Utilization: Incidence of Diseases

The increase in the incidence rate (per 1,000 population) of the diseases for which ultrasound imaging is useful has increased in recent years. Some of these increases have been quite substantial, such as a cumulative increase of more than 20% in the incidence of gallbladder, pancreatic, and liver disease over a four-year period. These diseases may be diagnosed using ultrasound on the abdomen or pelvis region.

Some of this increase may also be an increase in the rate of detection. Medicare began covering annual prostate exams and prostate-specific antigen (PSA) tests in 2000, which is in the period of our data, and per-population use of prostate ultrasound increased 5% between 1999-2001 and not at all from 2001-2003. It is reasonable to believe that the new coverage resulted in an increase to a higher level of utilization of follow-ups to PSA tests, including prostate ultrasound and ultrasonic guidance of prostate biopsy (as discussed below), but that once that adoption had happened, further increases above the current level may not result.

Outside of Medicare, pregnancy rates are soaring in women older than age 35, and these women are more likely to have pregnancy complications, including hypertension and diabetes. Babies born to older mothers are more likely to be born preterm or with a low birthweight. The risk of miscarriage doubles and the older a woman gets, the greater her risk of carrying a child with chromosomal abnormalities. Ultrasound would be indicated for any one of these factors, and many older mothers should expect several ultrasounds and possibly ultrasound-guided tests such as amniocentesis or chorionic villus sampling (CVS).

Appropriateness

In looking at most utilization data, the question remains: how do you distinguish appropriate utilization from inappropriate utilization? What part of growth is better access to screening or more people living longer with chronic disease, and what part is a redundant use of health care resources? Public and private payers struggle with these questions. But until we better know how to answer these questions, Congress, CMS and MedPAC should recognize that it is premature to label all growth as bad growth.

For instance, ultrasound-guided needle biopsy allows a physician to diagnose breast cancer without an open incision. The patient is spared time in the operating room, increased risk of infection, days off work and scarring. But on the Part B side of the ledger, two additional ultrasounds are scored—one for diagnosis and one to guide the needle. Marrying the hospital outpatient fee schedule and the physician fee schedule costs shows that needle-guided breast biopsy saves Medicare millions of dollars, but looking at the physician fee schedule alone shows only the cost of two additional ultrasounds.

In a study assessing appropriateness, conducted for Highmark Blue Cross Blue Shield, ob-gyns ranked highest among physician specialties in appropriateness, followed closely by urology, another specialty that has integrated the use of ultrasound in their practice.[14] Study authors attribute ob-gyns' high degree of appropriateness to the specialty's "relatively high degree of consensus" on imaging usage. Radiology and other specialties trailed in comparison. When broken down by diagnostic code, obstetric ultrasound was second only to mammography in overall appropriate usage at 86%. Ultrasound, generally, had an appropriateness score of 84%, far ahead of MRI and CT, both at 56%.

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[14] TG Dehn, B O'Connell, RN Hall, and T Moulton. Appropriateness of Imaging Examinations: Current State and Future Approaches. Imaging Economics. March/April 2000.

Defensive Medicine

Some imaging utilization growth, particularly within high-risk specialties like ob-gyn and in states that have not enacted tort reform, is undoubtedly attributable to the practice of defensive medicine. The fear of being sued leads physicians to sometimes perform additional procedures or tests, or refer to specialists.[15] Some estimates of defensive medicine costs, as a whole, run as high as $60-100 billion a year. It costs the federal government billions of dollars in Medicare and Medicaid spending and raises the cost of health care for every American.

The fear of being sued is justified. ACOG surveys members regularly on the issue of medical liability. According to preliminary data from the 2006 ACOG Survey on Professional Liability, the typical ob-gyn can expect to be sued 2.3 times over his or her career.[16] In fact, 89.2% of ob-gyns reported they had been sued at least once so far. Over one-third (37.3%) have been sued for care provided during their residency.

This high rate of legal activity does not equate to widespread malpractice. Rather, it demonstrates a lawsuit culture where doctors are held responsible for a less than perfect outcome. And in obstetrics, there is no guarantee of a perfect outcome, no matter how perfect the prenatal care and delivery.

A study published in the Journal of the American Medical Association surveyed physicians in 6 high-risk specialties in Pennsylvania and found that nearly all of them practiced defensive medicine (93%).[17] Within this group, 43% who detailed their most recent defensive act cited using imaging. This was true of a smaller but significant percentage of ob-gyns (18%).

Ultrasound adds a layer of reassurance to many ob-gyns and to their patients. Until Congress acts to solve America's medical liability crisis, the costs of defensive medicine, including imaging, will continue to grow.

Ultrasound is Different: Current Proposals Are Not Necessary for Ultrasound

Accreditation and Privileging

Some have offered proposals to require accreditation of physician practices in Medicare and in the private sector, or privileging beyond board certification.

Accreditation measures are unnecessary for ob-gyns, or other specialists, who are trained in ultrasound from the beginning of their residency and use it continuously and accurately throughout their medical career. Accreditation of medical practices is typically done to reduce exposure to radiation and to certify that technologists are using radiating equipment properly. This is not relevant to ultrasound, which doesn't use ionizing radiation.

Accreditation would also set a dangerous precedent of government intervention in patient care. If a physician needs special certification for ultrasound, then where would government accreditation regulations end? It would be unthinkable to parse medical practice into multiple government accreditation programs for each facet of clinical care, but that is just what is being proposed here.

Accreditation of ultrasound, an essential tool of private practice physicians, would be much more burdensome than accreditation for advanced imaging, largely found in imaging centers. Ultrasound is widely dispersed in physician offices. Harvey Klein,

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[15] Common Good and Harris Interactive. Fear of Litigation Study: The Impact on Medicine. Common Good, March 4, 2002.

[16] American College of Obstetricians and Gynecologists. 2006 ACOG Survey on Professional Liability. (Preliminary unpublished data) The 2006 ACOG Survey on Professional Liability administered between January 23 and March 20, 2006 by the American College of Obstetricians and Gynecologists. Results based on responses to self-administered mailed and electronic questionnaires. National response rate = 37%.

[17] DM Studdert, et al. Defensive Medicine Among High-Risk Specialist Physicians in a Volatile Malpractice Environment. JAMA. 2005; 293: 2609-2617.

Ph.D. of Klein Biomedical Consultants, a long-time ultrasound industry analyst, estimates that as many as 85 - 90% of ob-gyn offices in the United States have ultrasound on site for use in managing the care of their patients. One-quarter of ob-gyns are in solo practice and the mean practice size is three. These physicians do not have the office support staff on hand to manage the process of accreditation, unlike multi-million dollar imaging centers.

Furthermore, physician specialty societies, including ACOG, are already taking quality assurance measures, including participation in voluntary accreditation through the American Institute of Ultrasound in Medicine. Imposing a new layer of federal regulation on physicians will only increase practice expenses and require additional federal resources at CMS—already stretched beyond its means—for verification.

No federal certification or accreditation standards can guarantee that the right diagnostic test is provided in the right setting at the right time. This can only be accomplished through training programs and recommendations on indicated usage, like those promoted by ACOG.

Ultrasound has undeniable benefits for both patients and physicians needing prompt diagnosis and timely treatment. Its safety is high. Ultrasound is used appropriately in clinical settings. And it is growing at a slower rate than other Medicare imaging services and all Part B services generally. There is no compelling reason for the government to subject physicians, many in small practices and having many years of experience, to burdensome new accreditation requirements.

In-Office Ancillary Exception

Removal of the in-office ancillary services exception of the Stark Law (42 USC §1935nn) is an overly broad remedy, particularly in ultrasound. This change would restrict in-office diagnostic testing and result in substantial inconvenience and costs for patients, who would have to schedule a new appointment, with a different facility and a different physician, when the needed testing could be performed on the spot by the patient's own physician. Continuity of care would be interrupted, and the treating physician would lose valuable time in detecting and diagnosing a condition. An ob-gyn unable to perform ultrasonography would also lose the benefit of seeing real-time images, important in assessing fetal movement and blood flow.

Maryland's self-referral law--one of the toughest in the country—allows only radiology to self-refer for MR, CT and radiation therapy procedures, effectively limiting ownership of these technologies by nonradiologists. The law specifically excludes ultrasound. To the best of our knowledge, no state legislature has considered restricting in-office ultrasound.

Adopting the IDTF Certification Program in the Physician Office

Another proposal would expand certification requirements of independent diagnostic testing facilities (IDTFs) to the physician office. The IDTF certification program allows individual Medicare carriers to determine which specialties are able to supervise imaging exams, listed by CPT code. This approach would create a de facto privileging program under Medicare that is based on the physician's specialty rather than the training and experience of any specific physician or the guidelines that are derived by each specialty organization for its members. If applied to physician offices, ob-gyns in 12 Western states that use the carrier Noridian would be barred from supervising obstetric ultrasound, simply because they are not radiologists. The Medicare carrier in Wisconsin is considering similar restrictions for mobile imaging units.

Barring ob-gyns from performing ultrasound would clearly harm patient care. It also offers no protection from cost increases. The MRI, CT, and PET utilization growth in IDTFs far outpaces the utilization growth of these services in physicians' offices. MedPAC found that Medicare spending for IDTF services (mainly CT and MRI) nearly

doubled between 2000 and 2002, from $385 million to $741 million.[18] Medicare spending for all imaging services paid under the physician fee schedule grew at half that rate during the same period. MedPAC further found that Medicare spending for IDTF services grew by almost 40 percent per year, on average, during this period—a growth rate that cannot be explained due to the conservative growth in the number of new IDTFs.

Adjusting the Medicare Allowances for Use of Equipment and Interest Rates

In part of its calculation of the capital costs of equipment, Medicare assumes that imaging equipment is in use 50% of the time. CMS and MedPAC are investigating whether this assumption should be changed to a higher rate, a change ACOG would oppose. Ultrasound services are one element of the clinical care provided by physicians whose primary occupation is direct patient care - i.e. surgical procedures and office visits. Ultrasound equipment remains idle when physicians are engaged in other patient care activities, lowering its overall use rate. Breast surgeons, for example, will often have an ultrasound unit in their office for use on the one day a week that they perform ultrasound-guided needle biopsies and ultrasound-guided cyst aspirations in their offices. MRI and CT, on the other hand, are more often used in a radiology practice setting where imaging is the only type of care provided, and unlikely to sit idle during business hours. Given this use model for ultrasound equipment, we recommend that Congress direct CMS to maintain the 50% utilization rate for ultrasound equipment in order to maintain access to these important services for Medicare beneficiaries, even if CMS decides to change the utilization rate for other types of imaging equipment.

CMS indicated in its 2007 Medicare Physician Fee Schedule Notice of Proposed Rulemaking regarding practice expense that it currently utilizes an interest rate of 11% in calculating the cost of capital for medical equipment purchases. MedPAC, using commercial loan rates rather than medical equipment loan rates, argued during its April 2006 meeting that this rate is overly generous. Data obtained from Key Equipment Financing supports the accuracy of Medicare's current interest rate allowance. The last several years have seen historically low interest rates. During this time period the interest rate on the ultrasound equipment has ranged from 8%-10% (depending on the term and structure). In the last six months the low interest environment has changed, with the Federal Reserve Board boosting rates several times. As a result, rates have increased to 9%-11%. Before making any change on this interest rate, MedPAC or CMS should investigate the issue more fully by surveying a range of medical equipment financing companies.

Conclusion

Physicians in many specialties are trained in ultrasound from day one of their residency. ACOG and other specialty societies have shown leadership in developing appropriateness criteria and getting it into practice, and evidence of appropriateness shows that these efforts are working. Growth in ultrasound is low and driven by factors largely out of a physician's control, such as the increase in incidence of chronic disease and the tort climate. Setting it apart from other imaging services, ultrasound has a high record of safety, is fully integrated in day-to-day patient care, and is saving our health care system money every day through early detection and fewer invasive procedures.

A distinction between ultrasound and the rest of the imaging field is warranted. We urge the Congress, in any legislation, to recognize the safety, quality and appropriateness of ultrasound studies and to exempt ultrasound from any new restrictions on imaging use, federal quality standards, or additional administrative burdens.

MR. DEAL. Thank you.

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[18] MedPAC June 2004 Data Book.

Dr. Griffeth.

DR. GRIFFETH. Thank you, Chairman Deal and the distinguished members of this subcommittee for this opportunity to address the subcommittee and discuss the critical role of imaging in cancer care. As the Director of Nuclear Medicine at Baylor University Medical Center in Dallas, the Medical Director of the North Texas Clinical PET Institute, and the National Medical Director for PET for U.S. Oncology, I spend about 95 percent of my time focused on oncology patients and oncologic imaging. I have been asked specifically to address the utilization of advanced medical imaging, in particular, positron emission tomography, or PET scanning in the management of cancer patients.

But first, let me summarize that the growth of imaging utilization over the past several years is, in fact, saving the Government and other payers significant sums of money, improving the quality of healthcare, and allowing millions of Americans to lead longer, more productive lives. This is not just an evolution of technology; it is an evolution of patient care.

Advanced medical imaging is expensive, but medical imaging is absolutely crucial for the early detection, therapy selection, and follow-up of cancer patients. Let me stress this: if you or a family member is diagnosed with a life-threatening cancer tomorrow, it is virtually certain that the selection of your treatment and the follow-up of that treatment will be governed by advanced medical imaging. An imaging test such as a PET or PET CT scan can easily cost $2,000, but the therapy for a cancer patient can very quickly exceed $100,000. Medical imaging is absolutely critical to the selection and the targeting of those expensive therapies. Cost-effectiveness studies in various cancers have shown that utilization of PET or PET CT in appropriate circumstances can mean billions of healthcare dollars saved in this country per year.

But I am not here to focus on cost savings. Imaging quite simply provides better patient care. For example, PET CT imaging can prevent up to half of the futile surgeries that are performed for what turns out to be unresectable lung cancer. Substituting a $2,000 non-invasive imaging test for a $20,000 major surgery in a terminally ill patient makes good fiscal and clinical sense. The rise in utilization is overwhelmingly a positive occurrence for patients, as well as for healthcare budgets, and is due mostly to oncologists becoming more familiar with this vital new tool. Utilization will and should continue to increase as this physician education is ongoing.

It is clear that even with the very stringent criteria set out by CMS for utilization of appropriate PET in appropriate patients, less than half of those who qualify for a PET scan are actually getting that PET scan. CMS is losing hundreds, if not thousands, of dollars on each of those

patients that is not getting an appropriate PET scan, because that patient is therefore at risk for other needless and expensive procedures. In fact, CMS has always limited utilization of PET and dramatically limited over-utilization by imposing strict limitations on when a patient is even eligible to have a PET scan. Recently in recognition of the fact that these limitations are impeding both the appropriate care of many patients and our ability to learn more about when PET should be used in these patients, CMS has worked with the Academy of Molecular Imaging to establish the National Oncologic PET Registry, which allows for some expansion of the guidelines for use of PET in these patients and collection of data regarding PET's impact on patient management. This is a shining example of how CMS can work together with the imaging and oncology communities using what is commonly called evidence-based medicine to ensure appropriate future utilization. Several peers have also established guidelines regarding how often a cancer patient can have a follow-up PET scan. Some of these are unrealistic. Recently, I have been working with a group assembled by Dr. Mitchell Burkin of Trailblazer Healthcare aimed at establishing appropriate frequency guidelines for these patients, and I believe his approach could be duplicated on a larger scale by CMS.

In my opinion, collaborative efforts, such as those that I just mentioned, form the best way to balance optimal patient care with fiscal responsibility. Drastic reimbursement cuts will not decrease healthcare expenditures. They will limit access to advanced imaging tests like PET, and they will tend to push cancer care services back into the major medical center. This will lead to more expensive, less convenient, less integrated, and less effective patient care. Access to medical imaging must keep pace with advances in cancer therapy. To better see disease is to better treat disease. CMS should continue to work with imaging and oncology experts to develop appropriate management guidelines that includes and depends heavily upon advanced imaging.

I appreciate your attention and I look forward to any questions.

[The prepared statement of Dr. Landis Griffeth follows:]

PREPARED STATEMENT OF DR. LANDIS GRIFFETH, DIRECTOR, NUCLEAR MEDICINE, BAYLOR UNIVERSITY MEDICAL CENTER

Thank you, Mr. Chairman and distinguished members of the panel for giving me this opportunity to discuss the critical role of imaging in cancer care. My name is Dr. Landis Griffeth. I am the Director of Nuclear Medicine at Baylor University Medical Center in Dallas. I also serve as the Medical Director for the North Texas Clinical PET Institute and, for the past 6 years, the National Medical Director for PET for US Oncology.

My discussion today focuses on the use of advanced medical imaging, Positron Emission Tomography (PET) in particular, in the management of cancer patients. However, I want to make it clear that most of what I am saying extends to the treatment

of the other major diseases that take millions of American lives each year, such as cardiac or neurological diseases.

Turning to the role of imaging in cancer, it is important to consider several facts:

- 42 % of Americans will develop a significant cancer.
- 52% of those (almost 600,000 a year) will die from their cancer.
- Death rates from the four most common cancers—lung, breast, prostate and colorectal—continue to decline. Over the past decade, Americans have experienced a 7% decline in mortality from cancer and hundreds of thousands of lives have been saved—and imaging has played an important role in this progress.
- Imaging is used to diagnose, treat, manage, and predict disease.
- Many cancer patients will have their cancers detected or diagnosed by medical imaging.

More importantly, virtually 100% of cancer patients will have their treatment options determined by the results of one or more advanced imaging tests, and a large percentage of those patients will need multiple types of imaging tests and/or sequential imaging tests over time, to determine how well treatment has worked or whether tumor has recurred. Let me restate this – if you or a family member is diagnosed with a life-threatening cancer tomorrow, it is a virtual certainty that the extent of your disease, the treatment of your disease, and the assessment of whether or not that treatment worked will depend heavily on one or more advanced imaging tests.

The role of imaging in cancer care, in simple terms, is to diagnose and localize tumors, so that optimal decisions can be made about whether and how to pursue surgery, radiation therapy, chemotherapy, or any of the other extremely sophisticated therapeutic modalities that are now being developed at an encouraging pace.

The good news is that, over the past 40 years, along with dramatic advances in cancer treatment strategies, there has been an explosion of technological advances in imaging that have dramatically improved cancer patient care. These advances have led to earlier detection of cancer, when it is most easily and successfully treated, better selection of the appropriate therapies for each individual patient, better targeting of specific types of therapy, such as radiation therapy and minimally invasive surgeries, and better follow-up of cancer patients after therapy. Advanced imaging techniques such as mammography, sonography, CT, MRI, Nuclear Medicine and PET have played a huge role in helping us achieve better patient care, higher cure rates for limited cancers, and longer – and more productive – survival for patients with more extensive cancers.

While many of these new imaging techniques are expensive, we must consider the costs of imaging relative to the costs of treating cancer without the information that imaging provides and also with an eye to the efficacy of treatment without that vital information.

An imaging test, such as a PET or PET/CT scan may cost $2000 or so with the current payment schedule – clearly a lot of money. Surgery, radiotherapy, and chemotherapy for a cancer patient can very quickly exceed $100,000 – clearly significantly more money – and that is without some of the newer and more expensive treatment modalities, such as bone marrow transplantation. One paper published last year in the journal Cancer Biotherapy and Radiopharmaceuticals, studying patients evaluated for colon cancer that had spread to the liver, showed that incorporating PET into the work-up of these patients saved $5,269 per patient. In the US, there are 7000 colon cancer patients in this particular clinical situation. If all 7000 of these patients underwent PET imaging, this would save $37M. In patients undergoing initial staging evaluation of non-small-cell lung cancer, the global savings would be $267M (in 2003 dollars). Now I realize that $37M, or even $267M, is a very small amount compared to the types of budgets that you folks look at every day, but this is for two small subsets of the patients

in this country with cancer and, once again, shows that limiting access to advanced imaging is penny-wise and pound-foolish.

How do PET and other advanced imaging techniques save money? - Typically by showing that another costly procedure, like surgery or radiotherapy, is not indicated, or can be better targeted to improve patient results. The most extreme case would be a patient who is thought to have operable cancer, based on other tests, but in whom PET shows that the tumor has spread to other organs. The fact is that advanced imaging like PET helps make sure patients are treated appropriately.

This isn't just important from a cost-savings perspective; it is simply better patient care. The last thing any patient needs is surgery, radiotherapy, or chemotherapy that is either unnecessary or ineffective. For example, PET imaging can prevent up to half of the needless surgeries performed for lung cancer that is thought to be resectable, but, in fact, is not resectable. Imagine if you had inoperable metastatic cancer and only had six months to live. Would you rather have a $2000, non-invasive PET/CT scan that told you that it was inoperable, so that you could make the most of the time you had left, or would you rather spend a good part of your last six months recovering from a major surgery that cost $20,000 and that, in the end, didn't do you any good at all?

In addition, as cancer treatments become more expensive or more toxic to the patient, we need to be able to determine DURING therapy, preferably EARLY during therapy, whether that treatment is working or whether we should switch to a different type of therapy. To pursue a cancer treatment that is not working not only wastes thousands and thousands of dollars, but exposes the patient to needless side effects of treatment and, most importantly, delays the switch to another, hopefully more effective, type of therapy. In most tumors, imaging techniques like PET are the best means we have to determine whether a given treatment is working or not.

Moreover, as our treatments become more sophisticated, whether we are talking about better and better targeting of radiotherapy beams to avoid damage to non-tumor tissue or highly advanced types of gene therapies that very precisely target specific types of tumor cells, we simply cannot aim those big guns of cancer therapy correctly without the appropriate imaging techniques, whether they be CT, MRI, Nuclear Medicine, PET, or some combination of the above.

We also cannot forget that many cancer patients actually DIE from their treatments and from complications relating to their treatments, rather than from their disease. That is an unfortunate sequela of the need to use potentially very toxic agents to kill tumor cells. It is imperative that we use the best tools we have to allow us to target and refine those treatments.

I have been asked specifically to address the rise in utilization, and possible over-utilization, of PET and PET/CT, and to suggest ways to manage that utilization. My own impression is that the rise in utilization is a positive occurrence for patients, as long as it is appropriate utilization. I want to stress that increases in imaging utilization arise primarily from advances in patient care and not inappropriate use and are, in large part due to oncologists becoming more familiar with the use of PET in patient management. The large majority of medical oncologists and radiation oncologists currently practicing were not exposed to this relatively new modality during their training, and it sometimes takes a while for even very smart old dogs to learn new tricks. However, over time, when offered a tool that can be demonstrated to be more effective, and more cost-effective, at helping them make these life and death patient decisions, these physicians will, of course, adopt and utilize that tool.

Another factor in PET's growth has been the increased availability of this equipment – which not long ago was confined to major medical centers – in medium and small communities. I believe that this trend is bound to occur with any new and improved treatment or diagnostic tool, it's just that the growth curve is slower for complicated,

sophisticated modalities than it is for something that is easy to explain and distribute, such as a new antibiotic.

It should not be a surprise that the utilization of PET imaging has continued to grow rapidly over the past several years. It takes time to disseminate the knowledge and equipment necessary for appropriate utilization. In fact, even when we use the very stringent criteria developed by CMS for determining eligibility for a PET study, as well as VERY conservative estimates for the number of patients who will need a follow-up study to assess for effectiveness of treatment or for suspicion of a recurrence, far less than half of those patients who would probably benefit from a PET study are currently getting that PET study. Based on the cost-effectiveness projected for these PET studies, CMS is losing hundreds if not thousands, of dollars on each patient who does not get an appropriate PET scan, because that patient is, therefore, potentially at risk of undergoing other needless, expensive procedures. It is important to understand that imaging technologies detect cancer early, enable less-invasive cancer diagnosis and treatment, foster more effective cancer management, produce efficiencies and savings in cancer care, and, in many instances, keep workers more productive.

There also has been concern expressed over the "escalation of technology and expense," such as from CT to PET to PET/CT. This process is not just an evolution of technology, but an evolution of patient care. Sometimes, the benefits of this evolution, while clinically evident, are hard to quantify. For example, most studies, depending on the tumor type, show that combined-modality PET/CT scanning will provide answers that may range from 5-30% more accurate than separate PET and CT scans. But, the CONFIDENCE in the answer provided by this new technology can be up to 50% higher. When medical oncologists and radiation oncologists have greater confidence in the accuracy of these types of results, they can be more aggressive in their clinical decisions and treatments, they can spend less time and money with "second-guessing" procedures, and they can deliver better therapies that have a greater chance of killing the tumor cells and a lesser chance of needless side effects. Thus with the increased confidence of evolving imaging technology, oncologists provide better and safer treatment. Moreover, now that we have the appropriate tools to monitor tumor activity, we are seeing more rapid development of improved therapies, such as highly targeting radiation therapies and novel molecular approaches to cancer therapy, such as gene therapies or immunologic therapies.

As I just mentioned, CMS, as the hallmark of payer reimbursement has, in fact, limited utilization and dramatically limited over-utilization by imposing strict clinical guidelines for when a patient is and is not eligible for a PET study. CMS has recently acknowledged that those guidelines, in fact, are impeding both the appropriate care of many patients and the ability of the PET community, the oncologic community, and CMS to learn more about which patients should and should not undergo PET imaging. CMS has worked with the Academy of Molecular Imaging, the American College of Radiology, and others to address this problem by establishing the National Oncologic PET Registry, which allows for some expansion of the guidelines under which PET studies can be performed for Medicare's cancer patients, provided that data regarding the impact of PET on patient management are collected. This allows us and CMS to take an organized approach to expanding the use of a new modality into new patient conditions while gathering data to determine whether the new modality actually changes patient management and is, therefore, worthy of continued reimbursement for those conditions. This is a shining example of how the imaging community, the oncology community, and CMS can work together, using what is commonly called "evidence-based medicine" to ensure that a relatively expensive test is made available to patients who will benefit from it, while still limiting its use to appropriate situations.

In addition, several payers have also established frequency guidelines, based on the concern that repetitive testing is adding more cost than benefit to the patient care

equation. Some of those have been reasonable, while some, in my opinion, have not been adequately vetted in the real world of patient management. Recently, I have been involved in a PET stakeholder work group assembled by Dr. Mitchell Burken of Trailblazer, one of CMS's carriers, aimed at establishing appropriate frequency guidelines for various cancer conditions and patient situations, and I believe his approach should be duplicated on a larger scale within CMS. What I need to stress is that such clinical guidelines MUST be developed with input from the folks on the front lines: medical oncologists and radiation oncologists who are treating the patients and imaging physicians experienced in the use of PET in patient management. I would extrapolate those last comments to other imaging modalities.

While thoughtful, collaborative efforts such as those I just described are, in my professional opinion, the appropriate way to balance proper patient care with sound fiduciary responsibility, I don't see how the drastic spending cuts called for in the Deficit Reduction Act of 2005 will stop the inappropriate use of medical imaging. I am concerned that this legislation will deny access to the medical procedures that Medicare patients need. I admit to you today that I am not a businessman. I pursued a career in science and medicine, in part, to AVOID having to deal with business and finance. What I DO know is that the impetus, by both CMS and caregivers, over the past 15 years has been to push cancer care out into the community, while maintaining state-of-the art quality. This is good for the patients, who no longer have to drive long distances during their very serious illnesses for their diagnostic and therapeutic procedures. This is good for CMS and other payers, because community-based care is typically less expensive than care delivered in large medical centers. We believe that the drastic cuts in imaging reimbursement, particularly for PET and PET/CT, contained in the DRA constitute a serious threat to cancer care in the community. The estimates of the PET community are that the reimbursement cuts contained in the DRA could result in half of the non-hospital-based PET and PET/CT providers closing their doors, because they would be operating at a substantial loss. The net effect will surely be to push cancer care services back into the large hospital setting, translating into greater inconvenience and difficulty for patients and their loved ones and more expense for the healthcare system. Even worse, there are many patients who simply will not undergo advanced imaging tests like PET, because they are unwilling or unable to travel to a distant imaging center or because the lack of proximity means that their community physicians will remain unfamiliar with this life-saving technology.

We believe these cuts in reimbursement are arbitrary, and attempt to balance far too much of the overall healthcare budget on the small percentage that represents imaging. We also believe that there ARE no reliable cost data available by which to justify these cuts. The Academy of Molecular Imaging is currently trying to collate such data for PET and PET/CT and, at the very least, these drastic cuts should be delayed until reasonable and reliable cost data for both hospital and community outpatient care delivery systems can be gathered and analyzed.

In January 2000, the editorial board of the New England Journal of Medicine listed medical imaging as one of the eleven most significant medical advances of the past 1000 years, ranking on a par with the development of antibiotics and the elucidation of human anatomy and physiology.

The advancement of imaging science, and the ability of cancer patients in all communities across America to access these imaging techniques, must keep pace with the advances in cancer therapy. Optimal cancer care is absolutely dependent on optimal imaging care. To better SEE disease is to better TREAT disease, and the best treatments in the world may be useless if they are not targeted appropriately. To take our American cancer patients, who otherwise have access to the finest cancer care in the world, and restrict their access to high-quality imaging services such as PET, is the medical

equivalent of putting them in a very expensive, very fast, sports car – and then bashing the windshield with a ball-peen hammer.

Simply put, Draconian, across-the-board cuts in imaging reimbursement are NOT an effective way to cut overall healthcare costs. CMS should, instead, continue to work with experts in the related imaging and patient-care subspecialties to develop appropriate guidelines for patient management – management that includes, and depends upon, advanced medical imaging.

Mr. Chairman, thank you again for allowing me the opportunity to address you and your distinguished colleagues on this important issue.

MR. DEAL. Thank you.

Mr. May.

MR. MAY. Thank you. Mr. Chairman and members of the committee, my name is Lynn May. I am Chief Executive Officer of the American Society of Radiologic Technologists. Thank you for this opportunity to contribute to this important dialogue on the quality, safety, and cost of imaging services.

The ASRT represents more than 121,000 radiologic technologists, the healthcare professionals who perform medical imaging. Radiologic technologists work closely with physicians in a variety of medical settings, ranging from cardiac cath labs in hospitals to outpatient X-ray clinics. The images they produce help physicians diagnose disease, detect injury, and direct treatment.

Radiologic technologists operate some of the most complex equipment in the medical field, including MRI units, CT scanners, and gamma cameras. However, this amazing technology is ineffective in the wrong hands. That is because the quality of a medical image is directly linked to the skill of the person performing the exam. Individuals must have extensive education to perform exams correctly. Accurate medical imaging leads to accurate diagnoses, which leads to better outcomes for patients.

Unfortunately, tens of thousands of people who perform medical imaging in this country are not really qualified to do so. They have no formal education in the field, and they have no certification or license in the profession. That is because Washington, D.C. and nine other States do not regulate people who use diagnostic medical imaging equipment. In some States, a person can go from operating a forklift on one day to operating CT scanners in the next, with no training in between. And even in States where there are regulations, they vary so widely that there is no guarantee personnel are qualified. In many places, a hairdresser is more highly regulated than a nuclear medicine technologist.

Lack of Federal minimum standards for operators of equipment poses a danger to patients; that is why the ASRT, the Alliance for Quality in Medical Imaging and Radiation Therapy, and a large number of other organizations support the passage of the Consumer Assurance of

Radiologic Excellence, or CARE bill. I would like to thank Representative Pickering and Doyle for demonstrating their commitment to quality healthcare by introducing the CARE bill, H.R. 1426. The bill currently has 129 cosponsors, and it sets Federal minimum standards of education and credentialing for non-physician personnel who perform medical imaging examinations. To receive reimbursement from Federal healthcare funds for imaging procedures, States would need to regulate technologists according to these standards.

The CARE bill will improve medical imaging in three ways. First, the bill will improve quality. Patients rely on medical imaging for diagnosis, treatment, and cure, but any imaging procedure is only as effective as the person performing it. An exam won't reveal a broken bone or a diseased organ if the person using the equipment doesn't know the basics of anatomy, exposure, and technique. Poor quality exams can lead to additional testing, delays in treatment, and unnecessary anxiety for the patient. The Mammography Quality Standards Act proves that the establishment of personnel standards improves patient outcome. Under MQSA, people who perform X-ray exams of the breast must meet education credentialing and experience requirements. A study in Michigan concluded that breast cancer detection improved by one-third with the quality program that included educated and credentialed mammographers.

The CARE bill would not alter MQSA anyway, but the bill will ensure quality for all types of medical imaging exams, not just mammograms. People undergoing tests to diagnose a brain tumor deserve the same guarantee of quality that MQSA offers women undergoing mammography.

Second, the CARE bill will improve safety. When an X-ray exam has to be repeated because of improper technique, the patients receive double the radiation dose. Overexposure to radiation, as we know, can cause cancer, shorten lives, and cause birth defects in future generations. Taking an X-ray or a CT scan involves much more than pushing a button. Patients could be injured or even killed if the equipment is not properly used.

Third, the bill will reduce healthcare costs. More than 300 million medical images are performed in the United States every year. On average, 5.5 percent of these procedures have to be repeated. This means that thousands of defective medical images are being produced every day, and the Federal government pays for many of these mistakes. Medicare spent approximately $9.3 billion on medical imaging in 2003. If we can reduce the number of repeated exams by just one percent, Medicare would save well over $90 million a year.

Last year, as we know and as we have heard, the Medicare Payment Advisory Commission recommended the establishment of standards for personnel who perform medical imaging. The MedPAC report stated, "Establishing standards for medical imaging services would increase diagnostic accuracy and reduce the need for repeat tests, thereby improving the quality of care and helping to control Medicare expenditures."

The safety, quality, and cost of medical imaging procedures affects us all. Only competent personnel should be allowed to perform these procedures. H.R. 1426, the CARE bill, will ensure a minimum level of education, knowledge, and skill for those non-physician personnel who are responsible for medical imaging.

On behalf of the ASRT and the millions of patients that members of the ASRT serve, I ask this committee to move this legislation forward. Thank you.

[The prepared statement of F. Lynn May follows:]

PREPARED STATEMENT OF F. LYNNE MAY, CHIEF EXECUTIVE OFFICER, AMERICAN SOCIETY OF RADIOLOGIC TECHNOLOGISTS

Mr. Chairman and members of the Committee, my name is Lynn May, and I am the chief executive officer of the American Society of Radiologic Technologists. On behalf of ASRT's members, thank you for the opportunity to contribute to this dialogue on the quality, safety and cost of medical imaging procedures.

The ASRT represents more than 121,000 radiologic technologists, the health care professionals who perform medical imaging examinations. Radiologic technologists are non-physician health professionals. They work closely with physicians in a variety of medical settings, ranging from imaging departments and cardiac cath labs in hospitals to outpatient x-ray clinics. The images radiologic technologists produce can be the best tool a physician has to diagnose disease, detect injury and direct treatment.

Radiologic technologists operate some of the most complex equipment in the medical field, including MRI units, CT scanners and gamma cameras. However, this amazing technology is ineffective in the wrong hands. That's because the quality of any medical image is directly linked to the skill and competence of the person performing the exam. Individuals must have extensive education and training to perform the exam correctly. Accurate medical imaging leads to an accurate diagnosis, which leads to a better outcome for the patient.

Unfortunately, tens of thousands of people who perform medical imaging in this country are not qualified to do so. They have no formal education in the field, and they have no certification, license or credential in the profession. That's because Washington, D.C., and nine states around the country do not regulate the people who use diagnostic imaging equipment. In some states, a person can go from a job operating a forklift one day to a job operating a CT scanner the next, with no training in between. And even in states where there are regulations and laws, they vary so widely that there is no guarantee that personnel are qualified. In many places, a hairdresser is more highly regulated than a nuclear medicine technologist.

The lack of a minimum educational and credentialing standard for operators of imaging equipment poses a danger to American patients. That's why the ASRT and 30

other health, science and patient organizations support the passage of the Consumer Assurance of Radiologic Excellence bill, or CARE bill.

I would like to thank Representative Pickering for demonstrating his commitment to quality health care by introducing the CARE bill, H.R. 1426. The bill currently has 129 cosponsors. The bill sets minimum federal standards of education and credentialing for the personnel who perform medical imaging examinations. To receive reimbursement with federal health care funds for imaging procedures, states would be responsible for regulating technologists according to those standards.

The CARE bill will improve medical imaging in three important ways.

• First, the CARE bill will improve quality. Doctors and patients rely on medical imaging for accurate diagnosis, treatment and cure. But any imaging procedure is only as effective as the person performing it. An exam won't reveal a broken bone or a diseased organ if the person using the equipment doesn't know the basics of anatomy, exposure and technique. Poor quality exams can lead to additional testing, delays in treatment and unnecessary anxiety for the patient.

The Mammography Quality Standards Act is evidence that this approach works. Under MQSA, the personnel responsible for performing x-ray examinations of the breast must meet educational, credentialing and experience requirements. A study in Michigan concluded that breast cancer detection improved by one-third with a quality program that included educated and credentialed mammographers.[1]

The ASRT supports MQSA. The CARE bill would not alter MQSA in any way. But the CARE bill will ensure quality in ALL types of imaging exams, not just mammograms. Of the millions of medical imaging tests performed every year in the United States, only 10 percent of them are mammograms covered by MQSA. People undergoing general x-ray exams to detect pneumonia or MR scans to diagnose a brain tumor should have the same guarantee of quality that MQSA offers to women undergoing mammography.

• Second, the CARE bill will improve safety. When an x-ray exam has to be repeated because of improper positioning or poor technique, the patient receives double the radiation dose. Overexposure to radiation can cause cancer, shorten lives and cause birth defects in future generations. A June 2005 Public Health Service report listed radiation as a carcinogen and concluded that: "there is no dose of radiation, however low, that can be deemed completely safe."[2] Medical radiation should always be used judiciously and only when the benefit to the patient outweighs the risk. Taking an x-ray or CT scan involves much more than just pushing a button. Patients could be injured or even killed if this equipment is not used properly.

• And third, the CARE bill will reduce health care costs. Repeated imaging examinations cost the U.S. health care system millions of dollars annually in needless medical bills. More than 300 million medical imaging procedures are performed in the United States every year. If just one-half of one percent of those images is performed improperly, more than 4,000 defective medical images would be produced every single day. And the federal government pays for many of those mistakes. Medicare spent approximately $9.3 billion on medical imaging in 2003. The average repeat rate for imaging exams is 5.5 percent. If we can reduce the number to 4.5 percent, then Medicare would save more than $90 million a year.

In March of last year, the Medicare Payment Advisory Commission issued a report that recommended the establishment of standards for personnel who perform medical imaging. The MedPAC report stated, "Providers vary in their abilities to perform quality imaging procedures. Poor-quality studies can lead to repeat tests, misdiagnoses, and improper treatment. Establishing national standards for imaging services would increase diagnostic accuracy and reduce the need for repeat tests, thereby improving quality of care and helping to control Medicare spending."[3]

The safety, quality and cost of medical imaging procedures affects us all. Only competent personnel should be allowed to perform these procedures. H.R. 1426, the CARE bill, will ensure a minimum level of education, knowledge and skill for those who are responsible for medical imaging. On behalf of 121,000 ASRT members and the millions of patients they serve, I ask the committee to move this bill forward.

Thank you.

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1. Fintor L, Brown M, Fischer R, et al. The impact of mammography quality improvement legislation in Michigan: implications for the national mammography quality standards act. *Am J Public Health.* 1998;88:667-671.
2. U.S. Department of Health and Human Services, Public Health Service, National Toxicology Program. *Report on Carcinogens, Eleventh Edition.* Washington, D.C.; 2005.
3. Medicare Payment Advisory Commission. *Report to the Congress: Medicare Payment Policy.* Washington, D.C.; March 2005.

MR. DEAL. By the end of the year. I am sure that request was Mr. Pickering's as well.

Mr. Baumgartner, you are recognized.

MR. BAUMGARTNER. Chairman Deal, Congressman Pallone, distinguished members of the subcommittee, I am the CEO for Center for Diagnostic Imaging. I am pleased to be here on behalf of the National Coalition of Quality Diagnostic Imaging Services.

NCQDIS is a national nonprofit organization representing 2,400 outpatient imaging clinics and independent diagnostic facilities, otherwise known as IDTFs. I applaud the subcommittee for addressing this topic. NCQDIS believes that appropriate imaging utilization is vitally important. We define appropriate utilization as the right procedure at the right time, done right.

Our coalition has been actively engaged with CMS, recommending criteria to improve quality, reduce improper utilization, and better align Federal quality standards with those in the private sector. Above all, we appreciate that the focus of this committee is on ensuring the highest value in the services provided to the Nation's Medicare and Medicaid beneficiaries.

The good news is is that the savings can and should be achieved through appropriate utilization, while at the same time improving outcomes for beneficiaries through improved quality. We do not believe that the across the board reduction in payments as mandated by the DRA is the right approach.

For our members, such as my company, CDI, commitment to consistent quality standards and appropriate utilization has been critical to our success. It is important to note that as IDTFs, we rely on referrals from physicians. We cannot create our own demand for our services. We must prove to referring physicians and their patients that we are

worthy of their referrals. We believe this gives us a unique clinical perspective on appropriate utilization.

Today, I would like to focus on three primary recommendations.

First, we recommend that all diagnostic imaging providers be required to meet quality standards already set by CMS for IDTFs. I would like to cite for the committee a few examples. Unlike hospitals, IDTFs and physician offices are required to have physician supervision of all imaging procedures. IDTFs, unlike hospitals and physician offices, are required to have radiologists as supervising physicians, in some cases, Board-certified radiologists. In addition, IDTFs are required to have non-physician personnel be certified technologists, and furthermore, have written physician orders, unlike hospitals or physician offices that do not have to meet this criteria.

NCQDIS recommends that these quality standards established by CMS for IDTFs be applied to all outpatient imaging operations. Raising the quality bar across the board will protect beneficiaries from non-qualified imaging facilities, reduce repeat examination, and improve overall quality of care to the Medicare beneficiaries.

Our second recommendation is the continued support of public and private-sector efforts and setting consistent quality standards and addressing utilization. Private payers are taking action by implementing minimum quality guidelines and employing radiology benefit managers to make sure imaging is appropriately utilized. In addition, many States have sought to address utilization in imaging services. For example, Maryland does not permit non-radiologist physicians to refer to imaging equipment in which they have a financial interest. Other States have made it illegal for physicians to lease time on imaging equipment not located in their facility. Our members encourage these private-sector efforts and believe these steps will help ensure that beneficiaries receive a consistent standard of care, regardless of provider, and tests performed are medically appropriate.

Finally, NCQDIS supports a thorough analysis of imaging reimbursement as a critical component of value, recognizing that payment cuts will not reduce utilization and that attention to consistent quality standards will create better outcome for taxpayers and beneficiaries. By addressing utilization through rate cutting, rate cutting alone will have the unintended impact of encouraging providers who are able to control volume to increase referrals, thereby reducing any potential savings. Worse, rate cutting could lead to a lack of reinvestment in advanced imaging technologies, resulting in the use of old or ill-maintained equipment that produces poorer scans. The results will be missed or delayed diagnoses for beneficiaries, resulting in additional costs to Medicare.

I would like to point out that the NCQDIS members really have not seen this level of rate increase that others have seen. In fact, some of the major providers have shown a lack of growth completely, zero to negative growth in IDTFs.

Let me close by urging members of this subcommittee to support Congressman Pitts' legislation, H.R. 5704, requiring a comprehensive look at imaging reimbursement policy before any payment cuts are implemented.

NCQDIS sincerely appreciates this opportunity to testify and welcomes any questions.

[The prepared statement of Robert V. Baumgartner follows:]

PREPARED STATEMENT OF ROBERT V. BAUMGARTNER, CHIEF EXECUTIVE OFFICER, CENTERS FOR DIAGNOSTIC IMAGING

Chairman Deal, Ranking Member Brown, distinguished Members of the Subcommittee, my name is Robert Baumgartner, and I am the Chief Executive Officer for Center for Diagnostic Imaging Inc. I am very pleased to be here today as a representative for the National Coalition of Quality Diagnostic Imaging Services (NCQDIS), of which am a member of their Board of Directors.

NCQDIS is a non-profit organization, representing 2,400 outpatient imaging clinics and independent diagnostic testing facilities (IDTFs) throughout the United States. As described by Executive Director Cherrill Farnsworth, "NCQDIS and its members are at the forefront of medical technology, providing physicians and patients with the most state-of-the-art innovations, techniques and procedures available in diagnostic imaging."[1] I applaud the Subcommittee on Health for committing its time and resources to address today's important topic. As you know, it has been well-documented by the Centers for Medicare & Medicaid Services (CMS) and private payers alike that imaging utilization and spending have been growing at a rate faster than other health care expenditures. NCQDIS and its members believe that appropriate imaging utilization is an issue for both the public and private sectors, and you will learn about some of this coalition's related efforts today.

Our goal is appropriate utilization: the right procedure, at the right time, done right. NCQDIS has been actively engaged with CMS on this topic, recommending certain criteria that we believe CMS should consider in improving quality in imaging, reducing improper utilization, and better aligning federal standards with those in the commercial sector. But above all, NCQDIS firmly believes that the focus of this Committee should be on ensuring the highest value in the services provided to the nation's Medicare and Medicaid beneficiaries, and we believe that this can be done by providing clinically appropriate guidelines to all imaging providers that will have the net result of reducing over-utilization, and promoting the best possible care for beneficiaries. An across-the-board reduction in payments, as promulgated in the Deficit Reduction Act (DRA), without due consideration of the nuances of the imaging market and the resulting impact on beneficiaries will not improve quality or utilization and may, in fact, have the opposite effect.

My company, CDI, has been a leading provider of outpatient imaging services for 25 years. Our founder, Dr. Kenneth Heithoff, was one of the first physician pioneers to

[1] U.S. H.R. Comm. on Ways and Means, Health Subcomm., *Utilization of Medical Imaging*. 109th Cong. (February 10, 2005) (taken from prepared written testimony of Cherill Farnsworth, Executive Director, National Coalition for Quality Diagnostic Imaging Services (NCQDIS)).

advocate for more cost-effective, convenient and appropriate imaging services – and he did so originally by opening one of the first outpatient imaging centers in the country in 1980. Since that time CDI has grown to now serve 14 communities in Minnesota, Wisconsin, Illinois, Indiana, Missouri, Kansas, Florida and Washington. We are pleased to have received this year the distinction of "Number One Freestanding Imaging Group" in the U.S. by the readers of *Medical Imaging* magazine, a leading, national industry publication.

The principles of CDI are straightforward and unwavering: to deliver accurate, efficient diagnostic imaging services in an accessible and compassionate manner. To do so, we partner with specialized, board-certified, local radiologists in conjunction with community health systems, hospitals and physicians. For example, in St. Louis we have collaborated with St. Luke's Hospital as well as with the St. Louis Cancer & Breast Institute. In Minnesota, we are working with the Mayo Clinic in a small city and with a rural county-owned hospital and surrounding physicians, as well as providing convenient access for patients in the three main population centers of the state.

For CDI and other NCQDIS members, our commitment to consistent standards and appropriate utilization has always been critical to our success. As an independent imaging provider, we cannot create demand for our services. Let me underscore this point: the volume of procedures referred to NCQDIS members cannot be initiated or self-promoted, and we therefore represent an independent clinical viewpoint. We, like other IDTFs, must prove to referring physicians and their patients that we are worthy of their continued referrals. At CDI, we prove ourselves by maintaining a national, robust peer-review program, ongoing patient satisfaction surveys, sophisticated quality assurance initiatives, use of advanced imaging equipment, ACR accreditation of our MRI and CT scanners, electronic portal access to images and reports for referring physicians, and an insistence on radiologist specialization. Other NCQDIS members offer similar listings of service and quality indicators.

I. Industry Overview: Trends and Types of Providers in Outpatient Imaging

Before discussing specific utilization and quality topics, it is important to recognize the macro healthcare environment. Two significant national trends have and will continue to cause a natural and positive increase in diagnostic imaging utilization in the United States.

First, the use of imaging tests and procedures increases as we get older, and the 'Baby Boom' generation continues to age. By 2010, it is estimated that this generation will constitute 79 million people in the U.S.[2] Appropriate use of imaging procedures will play a crucial role in the early detection and treatment planning for the medical needs of these beneficiaries, so that overall costs on repeat exams, incorrect/non-concise and/or late-stage diagnoses and complications are avoided.

Second, demand for imaging services overall is also increasing due to advances in technology and applications. For example, new and less-invasive – yet efficacious and cost-effective – image-guided procedures are being developed and used as alternatives to costly and more invasive procedures like surgeries. Advanced applications, new contrast agents, refined scanners and new protocols are being brought to market and focused on specific medical specialties, benefiting patients with diseases or injuries such as cancer, neurological and cardiovascular diseases and musculoskeletal injuries (e.g. hips, knees and spines). As former Senator and Medicare Payment Advisory Commission (MedPAC)

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[2] Kimberly Scott, *2006 Diagnostic Imaging Industry Strategic Outlook: Market Trends & Analysis* (Wash. G-2 Reports 2005).

Commissioner Dave Durenberger recently noted, "Innovation is a value in healthcare and needs to be encouraged by policy."[3]

The Outpatient Diagnostic Imaging Environment

To better understand the issue of imaging utilization, it is important to understand exactly who provides imaging services. Imaging services are delivered in a variety of ways to Medicare beneficiaries.

First, an imaging procedure is performed only after a physician has evaluated a patient's condition and produced an order (similar to a prescription) for a specific imaging procedure that he or she feels is necessary to aid in the patient's diagnosis. The procedure has two components – the exam itself, and the radiologist's interpretation.

The imaging exam (the experience of the patient coming to the clinic and having the actual procedure done) is typically referred to as the "technical" component. Types of diagnostic imaging examinations include:

- MRI (Magnetic Resonance Imaging);
- CT or CAT (Computed Tomography);
- PET or PET.CT (Positron Emission Tomography);
- Ultrasound;
- X-ray;
- DEXA/Bone Densitometry;
- Mammography; and
- Nuclear Imaging.

After the "technical" imaging procedure is complete, the images are then sent for interpretation to a radiologist, who studies the images and delivers a written report back to the referring physician with the results of the imaging examination. Radiologists are physicians who must complete an additional 4 to 6 years of education and internships after completing their medical degrees before being licensed as a general radiologist. Fellowship-trained radiologists are further trained in specific areas of the anatomy or on specific imaging equipment, and require another two years of fellowship training.

Imaging equipment is owned, and technical services are provided by, a variety of sources.

The major provider segments are:

- Hospitals (both inpatient and outpatient);
- Independent Diagnostic Testing Facilities (IDTFs);
- Radiologist Offices; and
- Non-radiologist Physician Offices.

Hospitals typically provide both inpatient and outpatient imaging services at the hospital, and may also own imaging facilities geographically distant from the hospital campus to provide better community access. Hospitals are regulated facilities that provide on-site radiologists for required procedures and to supervise staff and assuring compliance with accreditation requirements such as JCAHO (Joint Commission on Accreditation of Healthcare Organizations). Hospitals provide imaging services for trauma patients, inpatient care and outpatients. Outpatient referrals come from on-staff hospital physicians, independent hospital physicians and community physicians.

Independent diagnostic testing facilities (IDTFs), which NCQDIS represents, are imaging facilities that exist outside the hospital setting and are not physically located in physician offices. They may be owned by hospitals, radiologists or investors. IDTFs have

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[3] David Durenberger, Presentation, *Defining the Medical Arms Race Syndrome* (National Institute of Health Policy, July 13, 2006) (Minneapolis, Minn.).

more rigorous federal regulations than other imaging providers; they must provide on-site radiologists for certain procedures, have qualified and certified technologists to operate the imaging equipment, and typically have their equipment certified by the American College of Radiology (ACR). Nationwide, there are approximately 5,000 IDTFs. As noted earlier, independent facilities, IDTFs cannot refer to themselves or create demand for their services. They provide service only after a physician has ordered an imaging procedure for his or her patient. IDTFs provide quick, convenient and high-quality access to imaging procedures that may not be available through the local hospital and generally provide same-day service for patients.

Radiologists may or may not own imaging facilities. Oftentimes radiology groups practice inside the hospital to provide interpretation services and consultation to hospital physicians. In certain instances, the radiologist may own the imaging equipment in the hospital or at hospital-based facilities. A radiologist may also own an IDTF in partnership with hospitals and investors. Radiologists also provide interpretation services to IDTFs and physician-owned imaging equipment. By law, radiologists are deemed not able to refer patients, and are considered independent imaging providers since they do not examine patients and order imaging services.

As a result of the in-office ancillary exceptions provided by Stark I and Stark II, non-radiologist physicians are able to install imaging equipment inside their offices or collaborate with other physicians to own or lease imaging equipment. In physician-owned imaging centers the primary source of referrals is from the physicians who own the equipment. Physician practices are not subject to the same requirements as IDTFs in terms of having a radiologist on site, nor are they required to have certified technologists as required for IDTFs.

NCQDIS believes this information to be critical in discussing consistency in standards, in understanding where and how over-utilization is occurring, and in discussing reimbursement.

II. Consistent Standards for All Imaging Providers: Assuring Value for Medicare and Medicaid Beneficiaries

NCQDIS and its members believe that the first step in consistent standards for all providers is the uniform application of IDTF regulations to all types of imaging providers.

Effective July 1, 1998, Medicare regulations provided for the implementation of the new provider designation of independent diagnostic testing facility ("IDTF")[4]. The IDTFs replaced the previous provider category of independent physiological laboratory (IPL). IDTFs are to be independent of a physician's office or a hospital, although either can apply to be an IDTF and therefore are not barred from meeting higher standards.
The Medicare carriers are charged with determining that all IDTF applicants meet the IDTF standards as required by CMS prior to enrollment and granting an IDTF applicant a Medicare billing number.

Arguably, the purpose of creating the IDTF classification was to ensure that diagnostic testing performed outside the traditional inpatient hospital or radiologist office setting met certain quality and safety standards, which also help to assure appropriate utilization. However, many believe that the Stark "in-office ancillary exception" has fostered the proliferation of imaging in physician offices, raising the question as to whether the goal of quality and safety has been achieved beyond the enrolled IDTFs. In fact, those entities that enroll and bill as an IDTF are disadvantaged from a competitive standpoint due to the regulatory requirements placed on the IDTF but not the other types of outpatient imaging entities. These include:

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[4] 42 C.F.R. § 410.33.

- **Supervising Physician Requirement**
  Currently Medicare Carriers are taking the position that, with limited exception for certain specialties, each supervising physician in an IDTF needs to be a radiologist. Some carriers have extended that definition to require board-certified radiologists. The goal of the regulations is clearly to ensure that the "supervising physician" oversee the quality of the testing equipment and the technologists who will be performing the tests utilizing such equipment. However, the Carriers place no such supervising physician requirements upon non-IDTF imaging providers such as outpatient hospital facilities or physician office imaging facilities;
- **Non-Physician (Technologist) Requirements in the IDTF Setting**
  The Medicare Carriers are given the authority to determine whether an imaging center technologist is qualified to conduct the diagnostic tests the IDTF is performing. Some Carriers have taken the position that such training and proficiency must be to the level of specific accreditation in the imaging modality in which the technologist is operating. This goes above and beyond state licensing or national credentialing of American Registry of Radiologic Technologists ("ARRT"). Thus, the Medicare beneficiaries who are receiving services in the IDTF setting are being treated by highly credentialed technologists under the supervision of radiologists. In other outpatient settings the technologists are not required to meet these same standards. Again, if having a technologist, who is not only certified but certified in a specific imaging modality, is important to have in place in an IDTF, then it should be important in all settings where Medicare beneficiaries are receiving outpatient imaging;
- **Written Orders are Mandated at IDTFs**
  While not clarified for physician offices, IDTFs are specifically required to proceed with care only with a written order in place. This small step is useful in assuring appropriate utilization. Certainly, if CMS is adhering to the quality components of patient safety and effectiveness, such a requirement is at least as important in a physician office setting or hospital.

To summarize, the following chart is a comparison of IDTF requirements to other imaging settings:

	Type of Imaging Provider		
CMS Criteria	**IDTF**	**Physician**	**Hospital**
Physician Supervision	Required	Required	Not Required
Supervising Physician Qualifications determined by Carrier (**Radiologist, and for many Carriers, Board-Certified**)	Required	Not Required	Not Required
Non-Physician Personnel (Technologist) Qualifications	Required	Not Required	Not Required
Written Orders	Required	Not Clarified	Not Clarified

Let me underscore: NCQDIS and its members are not seeking an advantage in either regulatory oversight or reimbursement, but rather, IDTFs are simply seeking a level playing field on which to operate. Advances in diagnostic imaging have led to tremendous strides in patient care: from reducing the need for invasive surgical

procedures to early detection of life-threatening diseases. However, imaging equipment and facilities operated by providers not specifically trained to provide complex diagnostic imaging services can be sub-optimal with regard to equipment quality, technologists operating the equipment, the quality of images produced, and ultimately interpretation of these diagnostic images. In addition, images taken by technologists who do not meet IDTF qualification standards may produce lesser-quality images that even the best-trained physician will have trouble interpreting.

Recommendation:

NCQDIS recommends that the existing IDTF regulations be used as a model to address all outpatient imaging operations, including those that fall under the Stark "in-office ancillary exception," hospital outpatient imaging facilities, and outpatient imaging facilities that are not enrolled in the Medicare program under the IDTF classification. This will guarantee progress in assuring appropriate utilization and offer more value for the beneficiary, as consistent standards will discourage non-qualified imaging facilities and reduce repeat examinations and diagnostically poor images caused by quality issues with either imaging equipment or staff.

III. Identifying, Measuring and Reporting Quality – Here and Now

NCQDIS has and will continue to advocate for Medicare's IDTF standards, as well as for additional community standards for the patients we serve. Several of our members have initiated efforts with their regional payers and purchaser-employers to identify community standards and best practices for imaging, and to measure and report their impact on utilization.

Identifying Quality Indicators

For example, CDI has been directly involved with an effort to identify best practices based on the components of quality as originally identified in *Crossing the Quality Chasm*, the landmark Institute of Medicine (IOM) series of reports.[5] We have found our mid-sized employers and collectively-bargained (Taft Hartley) Trusts are especially appreciative of this characterization because it is one that they can use with their employees/membership to help promote more knowledgeable consumers of value services. Below are several categories as an illustration that the goal of consistent standards for imaging providers is not a years-long process, but rather an attainable, short-term goal.

[5] Institute of Medicine, *Crossing the Quality Chasm: A New Health System for the Twenty-first Century* (Washington: National Academy Press 2001).

Indicators for Purchasing Value in Imaging

Categories are those identified by the IOM in *Crossing the Quality Chasm* to assist consumers in making value-based decisions about imaging providers.

Safety:

- ☐ MRI and CT equipment that have been accredited by a national accrediting body
- ☐ Registered Technologists
- ☐ Safety and Adverse Event Reports
- ☐ Active Peer Review Program with full participation of all radiologists
- ☐ Adequate and accessible Patient Education to assure the patient understands the procedure being undertaken and the risks of it.

Effectiveness

- ☐ Fellowship trained sub-specialists
- ☐ *Registered Technologists
- ☐ Online report access for treating physicians
- ☐ *Accredited MRIs and CTs
- ☐ Internal and Referring Physician Education - development and promotion of best practices.

Patient-Centered

- ☐ Access/Locations
- ☐ *Fellowship trained sub-specialists
- ☐ *Registered Technologists
- ☐ Patient Satisfaction data (tracked over time)
- ☐ *Patient Safety Records
- ☐ *Patient Education – customized to appropriate audience
- ☐ Cost competitive with providers maintaining similar standards
- ☐ Prohibition and/or reporting of Self-referral/ownership/leasing for any imaging services over $100

Timely

- ☐ Turn Around Time on Reports (average time from when patient comes in or referred to facility to when report arrives at treating physician)
- ☐ *Online Report Access for treating physicians (this might be a sub-head of previous item)
- ☐ *Patient Satisfaction data (i.e., patient's view of if service was timely)

Efficiency

- ☐ State-of-the-art Radiology Information System
- ☐ High-field equipment
- ☐ *Online Report Access
- ☐ *Access and Location, including evening and Saturday hours

Equity

- ☐ *Cost competitive with providers maintaining similar standards
- ☐ *Prohibition on Self-referral for any imaging services over $100
- ☐ *Reasonable Access/locations

Indicates item is used in more than one category of quality

Measuring and Reporting Indicators of Quality

Another project CDI has contributed to is a program to assist employees in choosing health care providers based on value, which is defined through the formula of:

Service, Access, Convenience, Safety, and Quality Outcomes

Cost

This measurement-for-public-reporting effort requires that imaging providers be measured based on three weighted-value categories. With this model, the score for professional services is weighted at 40%, a weight of 30% is given to each imaging facility, and another 30% designated for service and consumer satisfaction. In a June 30, 2006, communication to CMS Administrator McClellan, NCQDIS shared the specific measures included in each of these weighted categories and would be pleased to share the same with any Member of this Subcommittee. Currently, a white paper is in development which will link each of these indicators to peer-reviewed literature regarding specific best practices in imaging, or to another type of community standard, such as the CAHPS® Clinician and Group Survey.[6]

Other Marketplace Activities Related to Appropriate Utilization

Private payers have become not only aware of the potential for over-utilization of imaging services, they are taking action. Many private payers and purchasers have started to impose minimum quality standards for imaging facilities and equipment, and/or have hired third-party utilization review companies, often referred to as radiology benefit managers (RBMs).

As HealthHelp CEO Cherrill Farnsworth has explained:

> *"The second generation RBMs are encouraging and facilitating quality and safety. Measures such as tools for ordering the most appropriate tests and consistent quality standards for all imaging providers are saving 20-25% of total imaging costs. Cuts to reimbursement have been shown to save little or nothing. It is time that all payers, including CMS, reward quality and safety – and in the process, control over-utilization and costs. NCQDIS is happy to demonstrate this through actual case studies from the private sector."*

NCQDIS has spent the last year monitoring and collecting publicly available information from commercial payers and radiology benefits management companies (RBMs). We produced a tracking chart which we shared with CMS Administrator McClellan earlier, and which is appended to my testimony here today. Taken as a whole, the information on this chart indicates a sophisticated understanding by the majority of private payers that capital intensive imaging services must be managed in a more comprehensive manner than simply slashing reimbursement, and to encourage appropriate utilization.

In addition, many states have adopted more stringent Certificate of Need (CON) laws to review the need for higher-end equipment (such as MRI, CT and PET/CT) in the community before the equipment may be ordered. One state, Maryland, has passed a law that does not permit non-radiologist physicians to refer to imaging equipment or facilities in which they have a financial interest. Other states have made it illegal for physicians to lease time on imaging equipment which is not located in their facility and then bill for those procedures, essentially receiving a profit for each scan that they order.

Recommendation:

NCQDIS and its members not only support but strongly encourage private and public efforts to develop and utilize consistent standards for all imaging providers. In addition, NCQDIS supports efforts to restrict leasing of imaging time on equipment not located in the physician office. NCQDIS believes both of these efforts will help reduce

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[6] Agency for Healthcare Research and Quality, *Consumer Assessment of Healthcare Providers and Systems (CAHPS), CAHPS Clinician & Group Survey: Key Issues in Field Tests,* http://www.cahps.ahrq.gov/default.asp; path Work-In-Progress (accessed July 14, 2006).

imaging over-utilization by ensuring that beneficiaries receive a consistent standard of care regardless of provider, and that tests performed are medically appropriate and accurate.

IV. Parity in Reimbursement is Critical to Achieving Value in Imaging Services

In the current absence of consistent standards of quality for all imaging providers, cutting reimbursement seems the natural alternative to curbing over-utilization. However cutting reimbursement alone will not yield the desired effect, as value in healthcare cannot be measured by price.

Additionally, rate-cutting alone will likely have the unintended impact of encouraging some providers who are able to control volume to increase referrals to "make up the difference" in lost revenue, reducing any potential savings to CMS or its beneficiaries. Worse, rate-cutting could lead to a lack of reinvestment in advanced imaging technologies, and thus extended use of older or minimally maintained equipment that produces poorer scans. The result could be missed or delayed diagnoses for beneficiaries.

To be clear, NCQDIS and its members support parity in reimbursement for all imaging providers when consistent standards are met, but believe this parity must be determined carefully and in context of the different types of imaging providers and their business/cost structures, and of the reasoning behind current CMS reimbursement categories.

Medicare uses two reimbursement categories today for imaging services: HOPPS and MPFS. Hospitals are paid for outpatient services provided to Medicare beneficiaries through a methodology called Hospital Prospective Payment System (HOPPS). The HOPPS payment methodology was determined using the following process: Hospitals allocate costs for capital equipment, supplies, staff and other expenses into cost centers that they then submit in aggregate (with charge data) to CMS on an annual basis. CMS calculates a cost-to-charge ratio (CCR) for each department and for the hospital as a whole. HOPPS groups 'clinically similar' services together into Ambulatory Payment Classifications (APCs), whose costs are determined by multiplying each charge on every claim for a service in that APC by the hospital-specific CCR. The resulting HOPPS rate, in aggregate, is meant to reimburse the hospital for 82% of their costs.

Non-hospital outpatient imaging, independent diagnostic treatment facilities (IDTF) and physician offices are paid under a methodology called the Medicare Physician Fee Schedule (MPFS). MPFS bases payment for each imaging service on the costs associated with providing that service, including clinical staff, disposable supplies, capital equipment and administrative overhead. For each service provided, the MPFS assigns a payment rate based upon the actual costs of the services.

Unlike the MPFS, under which IDTFs are paid, HOPPS rate does not represent the true cost of providing imaging. The result of the methodology behind HOPPS is that neither the hospital, nor CMS, is able to identify the costs of providing individual imaging services within a particular hospital, especially over time. On the other hand, MPFS assigns a payment rate based upon the actual costs of each service.

It is also worth noting that hospitals receive additional payments from federal, state and local governments that are not available to non-hospital outpatient imaging providers. These additional payments are hospital-specific and are not figured into the national HOPPS payment rates. They include Disproportionate Share Hospital (DSH) payments for inpatient care (meant to offset the monetary losses hospitals incur when providing care to indigent patients), credit for bad debt, and, in some non-profit instances, tax-exempt bonding for capital expenditures and property taxes.

Last, hospitals provide a wide mix of services that subsidize one set of unprofitable services with others that are profitable. IDTFs instead concentrate on cost and quality of imaging services only.[7]

Recommendation

The disparity between HOPPS payment methodology and actual cost of providing individual services for IDTFs will lead to less competition in the imaging industry. Without a payment system that allows IDTFs to recoup actual costs of providing imaging services, IDTFs will not be able to meet consistent standards of quality nor improve services.

As mentioned previously, an IDTF cannot independently create demand for its services, and therefore relies upon providing quality services to attract the necessary demand.[8] It is therefore the position of NCQDIS that the discussion around quality and utilization is wholly ineffective and possibly counterproductive to have without including discussion on reimbursement. NCQDIS asks for the Members of this Subcommittee to consider the provision in H.R. 5704 that requires this comprehensive look at imaging reimbursement policy and we ask your support for it.

V. Conclusion

Medical advances are one of our society's great achievements, and the frail and elderly who depend on Medicare and Medicaid should be afforded the same access to this lifesaving and life-enhancing technology as those in the private sector. From the utilization perspective, rate cuts alone will not curb utilization. Congress and CMS have the tools to ensure this equality, and by promoting policies that move beyond short-sighted reimbursement-only methodologies to the more nuanced quality and value-based metrics such as those being used in the private sector, true parity for all imaging providers can be achieved, benefiting beneficiaries and taxpayers alike.

NCQDIS sincerely appreciates this opportunity, and we look forward to working with you and your colleagues, and the Administration, in the days ahead to address this important public need.

Appendix:

Private Payer / Radiology Benefits Management Activity
Related to Standards in Diagnostic Imaging

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[7] "Numerous studies show that when physicians or teams treat a high volume of patients who have a particular disease or condition, they create better outcomes and lower costs." Michael E. Porter, Elizabeth Olmsted Teisberg, *Redefining Competition in Health Care,* Harv. Bus. Rev. vol. 82(6), 64-76 (June 2004).

[8] "In healthy competition, relentless improvement in processes and methods drive down costs. Product and service quality rise steadily." Michael E. Porter, Elizabeth Olmsted Teisberg, *Redefining Competition in Health Care,* Harv. Bus. Rev. vol. 82(6), 64-76 (June 2004).

	CareCore National (For New Site or Modality Applications)	CareCore National (Standards for Continued Participation) *These standards will become effective 7/1/07	Anthem (Connecticut and Colorado)	Highmark (Pennsylvania)	HealthHelp RadSite® On-line assessment of an imaging provider's or physician practice's equipment, policies and personnel.	BCBS IL - AIM MA, PA & DE
CT	ACR Software ≤ 4 yrs old Min. 4 slices/rotation Min. 16 slices/rotation for CTA of lower extremities Min. 64 slices/rotation for Coronary CTA	ACR Min. 4 detectors ≤ 6 yrs old. Software updated within 3 yrs. Min. 8 detectors for virtual endoscopy Min. 16 detectors for CT angiography Min. 64 detectors for CCTA	ACR (Within 1 yr.) QC Program Multi-modality (3) MRA capability No extremity scanners Field strength of 0.5T or greater	QC Program Multi-modality (5) Radiation Safety Program **Staffing**: 10 day TAT Min. 40 hrs/wk on business days, including one evening/wk until 8 PM and 2 sat/month for a min of 4 hrs/day Highmark credentialed radiologist with current ACLS certification Licensed or certified tech	**Assessed for**: detector rows 1,2,4,8,16,32; Performance capabilities; Table capacity in lbs; intervention; gating; fusion imaging; CT cardiac imaging; CT angiography; fluoroscopy; year of manufacture, year of last upgrade; Typical annual volume of studies performed on this device; maximum number of work days of delay in scheduling patients; type of accreditation; active or expired; date of last physicist report deeming device satisfactory; average repeat rate for x-ray device as a percentage of exams performed; alignment light accuracy; slice thickness; high contrast resolution, low contrast resolution; image uniformity; noise; artifact evaluation; CT number accuracy and linearity; gantry-table alignment; gantry tilt; localization image from a SPR; accuracy of table incrementation; computed tomography dosimetry index; patient radiation dose for representative exams; scattered radiation measurement **Staffing**: : Medical Director - specialty, training, accreditation and certification; Are imaging studies interpreted by licensed and board certified radiologist?; Imaging Manager; Imaging device operators; Radiation Safety Officer. Policy and Procedure: Same as MRI	Various pre-authorization required
MRI	ACR & DICOM compatible Software ≤ 3 yrs old 0.30T- 0.6T and 1T devices manufactured prior to Dec. 31, 2001 limited to brain, spine, knees, and extremities. If devices above have gradient strengths of at least 20mT/meter and slew rates of at least 45T/meter/sec, can apply to perform additional studies by submitting images to show current capacity. 0.7T require ACR 1.5T or > device manufactured after Jan. 1, 2002 must provide service records indicating maintenance of hardware at original standards and major software upgrades ≤ 3 yrs old. Devices used for cardiac work must have EKG gating and at least 8 channel parallel processing. Devices used for breast MRI must be ≥ 1T and have bilateral capabilities. Devices 1T or > manufactured after Jan. 1, 2002 permitted to perform all exams.	ACR Hardware ≤ 6 yrs old. Software ≤ 3 yrs. MRA on 1.5T or greater	ACR or ICANL by Nov. 1, 2007 (Within 2 yrs) High performance full nng QC Program **Staffing**: Board certified in diagnostic radiology or nuclear medicine. Certified techs in Nuclear Medicine through ARRT or NMTCB 10 day TAT	ACR within 1 yr QC Program Multi-modality (5) MRA capability **Staffing**: 10 day TAT Min. 40 hrs/wk on business days, including one evening/wk until 8 PM and 2 sat/month for a min of 4 hrs/day Highmark credentialed radiologist with current ACLS certification Licensed or certified tech	**Assessed for**: equipment type, year of manufacture; year of last upgrade, typical annual volume of studies performed, accreditation, date of last physicist report, average repeat rate, center of frequency, table positioning, setup and scanning, geometric accuracy, high-contrast resolution, low-contrast resolution, artifact analysis, film quality control, visual checklist, magnetic field homogeneity, slice position accuracy, slice thickness accuracy, radiofrequency coil checks, inter-slice radiofrequency interference. **Staffing:** Same as CT **Policy and Procedure Assessment**: Interpreted on site; JCAHO accreditation; site visit inspection; expiration date of facility's current state x-radiation license; pediatric parameters; technique charts; collimation; referring physicians and family members' ownership or leasing arrangements with center; written report, physician present for contrast dosimetry monitoring devices.	Various pre-authorization required

	CareCore National (For New Site or Modality Applications)	CareCore National (Standards for Continued Participation) *These standards will become effective 7/1/07	Anthem (Connecticut and Colorado)	Highmark (Pennsylvania)	HealthHelp RadSite® On-line assessment of an imaging provider's or physician practice's equipment, policies and personnel	BCBS IL - AIM MA, PA & DE
PET	ACR or ICANL Sodium iodide detectors unacceptable regardless of configuration Must utilize a PET/CT machine PET/CT equipment older than 5 yrs must submit yearly reports that equipment is functioning per manufacturer's specifications	ACR **PET-only devices:** Hardware ≤ 6 yrs. old Software≤ 2 yrs. old Fusion software purchased/upgraded in last 2 yrs. **PET/CT:** No > 6 yrs. Old Software ≤ 2 yrs. Old	ACR or ICANL by Nov. 1, 2007 (Within 2 yrs) High performance full ring QC Program **Staffing:** Board certified in diagnostic radiology or nuclear medicine Certified techs in Nuclear Medicine through ARRT or NMTCB 10 day TAT	QC Program High performance full ring **Staffing:** 10 day TAT Performed by hospitals Techs certified in Nuclear Medicine through ARRT, CNMT, or NMTCB, or licensed by state.	**Assessed For:** Equipment type; gamma camera; performance capabilities: PET on gamma camera, SPECT, First pass, conventional, cardiac stress test, cardiac; year of manufacture; year of last upgrade; typical annual volume of studies performed; maximum number of work days of delay in scheduling patients; accreditation earned; accreditation expiration date; date of last physicist report deeming this device satisfactory; average repeat rate; sensitivity; energy resolution; count rate parameters; multiple window spatial registration; system safety interlocks; spatial resolution; intrinsic uniformity; dose calibrators; SPECT tomographic uniformity contrast and spatial resolution; SPECT center-of-rotation for multi-detector registretion calibration; SPECT high count floods for uniformity correction. **Staffing:** Same as CT **Policy and Procedure Assessment:** Same as CT	Various pre-authorization required
NUC MED	All SPECT capable with at least 2 detectors ACR or ICANL Cardiac Nuclear Imaging exclusive centers: single detector systems acceptable. Centers performing Cardiac and generalized SPECT studies: multi head systems required. Jaszczak Phantom acquisition every 6 months. SPECT mandatory Collimator Requirements: LEHR Low Energy (for High Resolution), Med. Energy (for Indium & Gallium), High Energy (for centers performing I131 whole body studies) Quality Assurance Requirements: Auto. Integral & Field Uniformity (computed) < 5%SPECT, COS & Floods (computed) < 1-2 pixels Cardiac Nuclear Imaging Requirements: Quantitative Analysis package, Gating, EF Calculated, Motion correction, back filter projection reconstruction, or line spread function software	ACR or ICANL Devices ≤ 5 yrs. old All SPECT capable w/ at least 2 detector heads Nuclear cardiology software ≤ 3 yrs. old	ACR or ICANL by Nov. 1, 2007 (Within 1 yr.) Imaging systems with capability of assessing myocardial perfusion and contractile function QC Program Inspection Record Echocardiography: Color Flow Doppler ICAEL by Nov. 1, 2007 (Within 2 yrs) **Staffing:** At least one board certified physician in diagnostic radiology, nuclear medicine, or is CBNC certified Certified tech through ARRT, CNMT, or NMTCB or licensed by state. Cardiac stress tests performed under ACLS or ARLS certified physician. 10 day TAT Echocardiography: Board certified in diagnostic radiology or cardiology	ACR or ICANL within 2 yrs QC Program Imaging systems with capability of assessing myocardial perfusion and contractile function. Radioactive Materials License Inspection Record Echocardiography: Color Flow Doppler capability ICAEL within 2 yrs **Staffing:** 10 day TAT Must employ at least one physician who is Highmark credentialed in diagnostic radiology, nuclear medicine or CBNC Cardiac stress tests performed under ACLS certified physician. Certified tech through ARRT, CNMT, or NMTCB, or licensed by state Echocardiography: Credentialed by Highmark and/or Keystone Health Plan West in diagnostic radiology or cardiology	**Assessed For:** Equipment type, year of manufacture; year of last upgrade, typical annual volume of studies performed; maximum number of work days of delay in scheduling patients; accreditation earned, expiration date of accreditation, date of last physicist report deeming this device satisfactory, average repeat rate as a percentage of total number of images produced, sensitivity, energy resolution, count rate parameters, multiple window spatial registration, system safety interlocks, spatial resolution, intrinsic uniformity; dose calibrators; SPECT tomographic uniformity, contrast, and spatial resolution; SPECT center-of-rotation for multi-detector registration calibration; SPECT high count floods for uniformity correction. **Staffing:** Same as CT **Policy and Procedure Assessment:** Same as CT	Various pre-authorization required

	CareCore National (For New Site or Modality Applications)	CareCore National (Standards for Continued Participation) *These standards will become effective 7/1/07	Anthem (Connecticut and Colorado)	Highmark (Pennsylvania)	HealthHelp RadSide® On-line assessment of an imaging provider's or physician practice's equipment, policies and personnel	BCBS IL - AIM MA, PA & DE
Plain Films			• QC Program • Automatic processor **Staffing** • Tech licensed by state or other state recognized entity, or certified by the ARRT, ACRRT, ASPMA • 10 day TAT Other: • Board certified radiologist to over-read films within 5 business days.	• QC Program • Automatic processor **Staffing:** • 10 day TAT • State licensed or ARRT certified tech		Not Listed
Other Notes		• Accredited equipment that doesn't meet age requirements, may be used for back-up or overflow purposes	• Owned by the provider or leased by the provider on a full-time basis • Subject to unannounced site inspections • Restrictions/Review on imaging at Multi-Specialty Group Practices	• Will reimburse providers for services on imaging equipment (i) owned by the provider or (ii) leased by the provider on a full-time basis.	HealthHelp also offers... • RadConsult® An evidence -based alternative to pre-certification that enhances physician's ability to order appropriate diagnostic imaging by giving them the latest information • RadCert® A traditional pre-certification program with an educational edge • CodeRight® A claims-review program for radiology claims, ensures correct provider billing and correct payment • RadScope® Helps payers maintain quality patient care by helping them purchase imaging services from physicians who have been trained in an accredited medical school for specific imaging procedures • RadExcel® is an on-line ACCME-accredited education program designed to improve ordering among nonradiology specialist	

MR. DEAL. Thank you.

Dr. Rucker.

DR. RUCKER. Thank you. My name is Don Rucker. I am Vice President and Chief Medical Officer of Siemens Medical Solutions, United States, and I am also a practicing emergency department physician. I am testifying today for the National Electrical Manufacturers Association. NEMA represents the manufacturers who provide about 90 percent of the world's imaging equipment and NEMA has been the standard-setting organization for imaging equipment for many decades, leading to an extraordinary high level of quality in that equipment.

Thank you for holding the hearing today about Medicare patients and the care they receive. You have heard a lot of testimony about various perspectives on growth in imaging services. We believe that the tremendous advance in science is by far the main reason for growth in imaging. This is a worldwide phenomenon. It is actually independent of reimbursement schemes and by country.

To understand that, I think it is worth understanding modern imaging devices: ultrasound, CT, MR, PET scanners are computers. Almost half of our cost of goods in these devices is actually software, and as you know, computer power has been doubling every 18 months for decades. So when you look at what has been going on in imaging, I think if you see these things as computer devices it gives a little bit of perspective on this. Let me just give an example about CAT scanners, computer tomography, to spell it out. About 10 years ago, CAT scanners became advanced enough in resolution that you could see the appendix. When that happened, you eliminated lots of exploratory laporotomies and the notorious observation admit where we just see if the patient got worse. Five years ago, CAT scanners gained enough resolution to be able to look at 5 milliliter dropoffs in blood vessels in the lung. Now, you can actually look at pulmonary embolus blood clots in the lung, eliminating the need for what are known as ventilation profusion scans, eliminating the need for pulmonary angiography. Today, high resolution cardiac CT scanners are so fast and so accurate that we can stop in the middle of a heartbeat and look at coronary arteries, a resolution detail of 2 to 3 millimeters. This will certainly, as this technology comes on, reduce hospital admissions for chest pain as well as a number of diagnostic cardiac catheterizations, huge cost savings.

In talking about imaging, I think often statements about self-referral are blended in with statements about imaging growth. It is worth understanding, certainly as we look at the Medicare data, that in fact the growth of imaging has been pretty much uniform by all physicians, whether they have any opportunities for self-referral or not. This is true

by ordering physicians who have absolutely no way of making money and for whom ordering a study incurs incremental costs and time that are not directly reimbursed.

It is also worth noting that when you look at some of the data that the mix of imaging studies is remarkably constant. The top five: heart, brain, spine, abdomen, and extremities actually don't change from a year-to-year basis. I mean, they are almost like constants of nature, which suggests that specialty-specific self-referral, while it certainly goes on on some level, is probably much smaller than we think, possibly based on the assumptions that increased utilization is equivalent to inappropriate utilization or mis-utilization. The Deficit Reduction Act makes what we feel are disproportionate cutbacks in medical imaging. As other witnesses have testified, these cutbacks have a randomizing effect. The philosophy there also absolutely does not address the billions of dollars of cost savings from having precise diagnoses, and that is something I think that Medicare and CMS and MedPAC really need to look at. NEMA feels that these large cuts will slow the adoption of imaging technologies, will slow down the option of earlier diagnosis for Medicare patients, and less invasive treatment. We would like to thank Congressman Pitts and the members of the committee and subcommittee who have sponsored H.R. 5704 to reassess these cutbacks in this broader context.

I would like to conclude by suggesting that imaging is growing not because of self-referral or sort of devious things, but because physicians would like to provide Medicare patients with precise answers and targeted treatment, rather than educated, I would like to think highly educated, but nevertheless, educated guesses and empiric therapy. Medicare reimbursement policy should reflect the true cost of providing imaging and Medicare reimbursement policy should reflect the total cost of providing care, not just the 10 percent most divisible in imaging costs.

Thank you very much.

[The prepared statement of Dr. Donald W. Rucker follows:]

PREPARED STATEMENT OF DR. DONALD W. RUCKER, VICE PRESIDENT AND CHIEF MEDICAL OFFICER, SIEMENS MEDICAL SOLUTIONS USA, INC.

Mr. Chairman and Members of the Subcommittee:

My name is Donald Rucker. I am a practicing emergency physician and serve as Vice President and Chief Medical Officer of Siemens Medical Solutions USA. I am speaking today on behalf of the National Electrical Manufacturers Association.

NEMA is the largest association representing medical imaging manufacturers in the world. It represents companies whose sales comprise more than 90 percent of the global market for X-ray imaging, computed tomography (CT), radiation therapy, diagnostic ultrasound, nuclear medicine imaging, magnetic resonance (MRI), and medical imaging informatics equipment.

NEMA is also the world's primary standards-development organization for medical imaging equipment. Such standards establish commonly-accepted methods of design, production, and distribution for medical imaging products. Sound technical standards benefit the user and patient, as well as the manufacturer, by improving safety, fostering efficiencies, and assisting the purchaser in selecting and obtaining the appropriate product. We have been setting standards for 75 years.

I want to thank the Chairman for conducting this important hearing on imaging. On behalf of NEMA, I also want to thank the Subcommittee members who have taken steps to ensure continued beneficiary access to critical imaging services.

Summary and Overview

In my testimony today, Mr. Chairman, I wish to leave the Subcommittee with several points:

Scientific Advances are the Primary Reason for Imaging Growth: The primary drivers of imaging utilization are the dramatic scientific and technical advances that allow physicians to see soft tissues and organs inside the human body. The power of imaging to offer more precise and less-invasive care has sparked what can only be described as a fundamental transformation in medicine. Physicians can now use imaging for more conditions, for more patients, and for a much broader array of purposes than ever before. Modern imaging devices today are sophisticated computers, and the imaging power behind them continues to grow in parallel with the growing computing power that drives so many other sectors of the economy.

Medical Imaging Has Become a Standard of Care: Given this new ability to make specific diagnoses—rather than educated clinical guesses—before treating a patient, physicians have incorporated medical imaging into practice patterns across medical conditions and diseases. In fact, imaging has become a standard of modern care for virtually all major medical conditions and diseases. This includes cancer, stroke, heart disease, trauma, and abdominal and neurological conditions.

Utilization Growth Arises from Complex Causes: No one can doubt that financial incentives play a role in the use of imaging. But the impact of these incentives pales in comparison to these broad, patient-centered changes. Interestingly, growth in utilization is remarkably similar across medical specialties that can bill for imaging and those that cannot. Growth in utilization is also remarkably consistent across organ systems, suggesting that a desire to address patient care questions is behind the growth, not practice changes by specific medical specialties.

Continued Innovation and Patient Access Require Informed Policies: Public policies that influence the use of medical imaging—including reimbursement decisions such as the Deficit Reduction Act of 2005—must take into account this fuller view and richer context of utilization growth. Basing imaging reimbursement policy almost purely on year-over-year growth rates overlooks these deeper realities and patient desire for diagnostic certainty.

I will elaborate on each of these today, Mr. Chairman, before turning to our policy recommendations on reimbursement of imaging and issues directly related to growth in the use of imaging.

Scientific Advances are the Primary Reason for Imaging Growth

As a first step, it is important to explore why imaging has become such a driving force in how physicians practice and how medical delivery is structured.

For centuries, physicians diagnosed patients by using the physical examination. With the advent of plain film x-rays a little over a century ago, physicians could see bones and outlines, as well as shadows of some organs such as the heart and the lungs. Today, with modern imaging devices, physicians can see every single soft tissue, organ, and clinically significant blood vessel. Complemented by a parallel, computing-based

revolution in genomics, we simply have the opportunity to take care of patients in entirely new ways. In this context, it does not seem surprising that Medicare is seeing rapid growth in these clinical practices.

How has medical imaging technology transformed health care?

Redefining Care: Advances in imaging have provided physicians with new tools to improve care and do so in new ways. As a result, they use imaging in more clinical situations, for more diseases, and for more patients.

- Diagnosis of heart disease was once confined to a stethoscope and an EKG. Today, physicians use imaging procedures such as cardiac catheterization, CT angiography, cardiac ultrasound, and nuclear imaging to address heart disease. These foster early diagnosis and treatment and improved survival.[1] With intravascular ultrasound, the very basis of coronary artery care has moved from treating "hardening of the arteries" to addressing "vulnerable soft plaque".
- For decades, cancer physicians were limited to guesswork and indirect evaluations in judging the effect of cancer drugs on a tumor. Today, PET scans allow them to visualize the tumor on a individual cellular level, determine how well cancer drugs are working, and calibrate therapy to the patient's exact circumstances.[2]

New Information for Diagnosis and Planning: Imaging has also brought about significant change by providing physicians with vast amounts of new information and visualization for every body part. This allows them to diagnose disease and plan treatment more effectively and confidently.

- CT and MRI now allow physicians see the blood vessels in the brain and the precise location of a stroke—reducing guesswork—and guide them in choosing between surgery or clot-busting drugs.[3]
- Physicians use CT and MRI, rather than surgery, to visualize and pinpoint brain tumors and aneurysms—even view them in 3D.[4] This gives them critical information about the approach to treatment, sparing as much normal brain tissue as possible.

As these examples also show, the power of medical imaging is increasingly blurring the lines between diagnosis and treatment delivery.

Less-Invasive Treatment: Medical imaging has also transformed medicine by enabling physicians to provide medical treatments deep within the body without surgery, blood loss, or their related risks. So care is easier, complications fewer, and recovery is faster. As a result, patients who may have avoided surgery or whose health conditions did not allow surgery may now elect to receive care.

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[1] See Mowatt G, Brazzelli M, Murray A, Fraser C, Vale L. Systematic review of single photon emission computed tomography (SPECT) myocardial perfusion scintigraphy for the diagnosis and management of angina and myocardial infarction. Nucl Med Commun. 2005 Mar;26(3):217-29. Also see Alan S, Ulgen MS, Ozturk O, Alan B, Ozdemir L, Toprak N. Relation between coronary artery disease, risk factors and intima-media thickness of carotid artery, arterial distensibility, and stiffness index. Angiology. 2003 May-Jun;54(3):261-7. Also see *The Value of Investment: Better Care, Better Lives*, by MedTAP International, February 2004.

[2] "Positron-Emission Tomography and Assessment of Cancer Therapy," Juweid, ME, Cheson, BD, *New England Journal of Medicine,* 2006 354: 496-507.

[3] "Diagnosis as a Guide to Stroke Therapy," *The Lancet*, Vuadens P, Bougousslavsky J, 1998: (suppl III) 1014. Also see "Practice Guidelines: Use of Imaging in Transient Ischemic Attacks/Acute Stroke," A Report of the Stroke Council, American Heart Association, *Stroke*, 1997; 28: 1480-1497; and "Stroke Tests," American Stroke Association at www.strokeassociation.org, and

[4]See White PM, Wardlaw JM, Easton V. Can non-invasive imaging accurately depict intracranial aneurysms? A systematic review. Radiology. 2000 Nov;217(2):361-70.

- Screening for abdominal aortic aneurysms now allows elective surgery or even minimally invasive aortic stent placement preventing largely fatal aortic aneurysm ruptures.[5]
- Physicians can now use image-guided embolization to correct uterine fibroid tumors without a hysterectomy. This permits patients to get back to work in two weeks, rather than six.
- Physicians can use stereotactic radiosurgery which targets very narrow but extremely powerful beams of radiation on small brain tumors and early metastases. The procedure requires no hospitalization and substitutes for brain surgery.

Substitution for Other Health Care Costs: Innovations in medical imaging also provide physicians with new capabilities to substitute imaging for other interventions or procedures, including observation days in the hospital.

- Physicians can use ultrasound to guide them in placing large-bore intravenous catheters in central veins—substituting for blind guesses about where the vein is located. The result is reduced pain and complications—and shorter hospital stays.[6]
- With high resolution CT scans, physicians can now precisely diagnosis appendicitis. As recently as several years ago, the standard of care for possible appendicitis included hospital admissions to observe for clinical deterioration and exploratory surgery to enable the surgeon to look directly at the appendix and see whether it needed to be removed.[7]
- CT scans can tell physicians whether a pulmonary embolism has developed in the lung, thereby reducing the need to thread a catheter through the heart to reach the lung.[8]
- Intensity-modulated radiation therapy allows physicians to pinpoint tumor location and "sculpt" each beam of radiation, thus avoiding harm to surrounding healthy tissue.[9]

New Settings of Care: Medical imaging is now smaller and more portable, enabling care in a variety of new settings such as physician offices and imaging centers. For

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[5] "Community-Based, Nonprofit Organization-Sponsored Ultrasonography Screening Program for Abdominal Aortic Aneurysms Is Effective at Identifying Occult Aneurysms," Ogata T, Arrington S, Davis PM Jr, Sam AD 2nd, Hollier LH, Tromp G,Kuivaniemi H., *Ann Vasc Surg*. 2006 Apr 27; [Epub ahead of print]

[6] "Ultrasonic Locating Devices for Central Venous Cannulation: Meta-Analysis," Daniel Hind, et al, *The British Medical Journal*, Volume 327, 16 August 2003

[7] "CT Evaluation of Appendicitis and its Complications: Imaging Techniques and Key Diagnostic Findings," Pinto Leite N, Pereira JM, Cunha R, Pinto P, Sirlin C.,AJR Am J Roentgenol. 2005 Aug;185(2):406-17. Review.

[8] "Multidetector-Row Computed Tomography in Suspected Pulmonary Embolism," Perrier, et. al., *New England Journal of Medicine*, Vol 352, No 17; pp. 1760-1768, April 28, 2005. Also, "Clinical Validity of a Negative Computed Tomography Scan in Patients with Suspected Pulmonary Embolism: A Systematic Review," Quiroz, et al., *Journal of the American Medical Association*, Vol 293, No 16; pp. 2012-2017, April 27, 2005.

[9] See "High Dose Intensity Modulated Radiation Therapy for Prostate Cancer: Early Toxicity and Biochemical Outcome in 772 Patients," by Zelefsky MJ, Fuks Z, Hunt M, Yamada Y, Marion C, Ling CC, Amols H, Venkatraman, ES, Leibel S, in *International Journal of Radiation Oncology, Biology, Physics*, Volume 53, No. 5; pages 1111-1116, August 2002. Also see "Cancer in the Crosshairs," Brown E, *Forbes*, p. 364, October 28, 2002.

patients, the result is convenience and easier access—increasing the likelihood they will get the tests, treatments, and follow-up they need.[10]

- Shrinking ultrasound machine size allows physicians to diagnose cardiovascular, obstetrical, abdominal, and many soft tissue problems in independent imaging facilities, physician offices, and other non-hospital locations as well as at the patient's bedside. Hand-carried ultrasound machines are used in emergency rooms, ambulances, and even on the battlefield.[11]
- Similar changes are occurring in other imaging technologies, including digital radiography, CT, and MRI. These technologies now allow diagnosis and treatment in a variety of non-hospital settings.

The Computer Revolution and Imaging: Modern imaging devices are in large part sophisticated computer systems that perform incredible transformations of signals acquired via sound waves, x-ray beams, or radio frequency waves and proton spins. Computing power over the last 40 years has in fact grown as described by "Moore's Law", a remarkable prediction by Gordon Moore, one of the founders of Intel, who stated back in 1965 that, as far as he could see, computing power would double every 18 months. For Medicare patients and physicians, this has come to mean that every two to three years, entirely new aspects of the body come into focus and, what was before a clinical guess is now a precise answer from an imaging study.

Mr. Chairman, I want to stress that any of these trends individually would have been enough to bring about important improvements in medical care. Taken together, however, they have brought deep change to the health delivery system:

- Diagnosis is earlier than ever.
- Physicians have more information and insight.
- Care is less invasive and less painful.
- Access to tests and treatments is easier as imaging procedures are available in convenient settings.
- Patient outcomes—from fewer complications to saved lives—are dramatically improved.
- System-wide savings and efficiencies abound.

Medical Imaging Has Become a Standard of Care

Another factor in the transformation of medicine is that imaging has become a standard of modern care for virtually all major medical conditions and diseases.

Heart Disease

One of the most dramatic contributions that imaging has made over the past 30 years has been its role in the significant reductions in mortality and morbidity of heart disease.[12] Advances in cardiac imaging have enhanced every aspect of cardiac care, including screening, diagnosis, treatment, and follow-up monitoring—providing detail unachievable even a decade ago.[13] Cardiac catheterization, ultrasound, and CT scanning

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[10] See "Travel Distance to Radiation Therapy and Receipt of Radiotherapy Following Breast-Conserving Surgery," Athas WF, et. al., *Journal of the National Cancer Institute,* Vol. 92, No. 3, February 2, 2000, pp. 269-271.

[11] See "The Incredible Shrinking Ultrasound Machine," Elsberry, RB, *Imaging Economics,* Nov. 2001.

[12] See *The Value of Investment: Better Care, Better Lives*, by MedTAP International, February 2004. Also see "Trends in Heart Attack Treatment and Outcomes, 1975-1995, Literature Review and Synthesis," by Paul Heidenreich and Mark McClellan, in *Medical Care Output and Productivity,* edited by David M. Cutler and Ernst R. Berndt, University of Chicago Press, 2001.

[13] See Lewin Report, p. ii. Also see Alexanderson E, Granados N, Gomez-Martin D, Ricalde A, Meave A. [Evaluation of coronary artery disease by myocardial perfusion imaging in women] Arch

provide physicians with vital information and precise images of blood flow, artery blockages, and heart functioning.[14] This information allows physicians to make earlier, more accurate diagnoses and to better target therapy. Also, medical imaging facilitates coronary angioplasty which has become the therapy of choice for opening clogged arteries and has been shown superior to drugs in more than 20 clinical trials.[15]

Advances in imaging continue to offer new insights and detail about cardiac activity. Today, multi-slice CT provides rapid images of coronary artery plaque and precise visualization of clogged arteries without use of invasive catheters.[16] In addition, MRI and nuclear imaging scans show functioning of the heart muscle at the cellular level allowing effective treatment of CHF, one of Medicare's most costly illnesses.

Stroke

Medical imaging has made modern stroke therapy possible through early, accurate diagnosis and new treatment options.[17] Numerous imaging technologies, such as ultrasound and MRI, provide high-resolution images of the vascular system, and the brain to identify blockages or the thickening of the artery lining, thus allowing stroke prevention. CT scans, diffusion-weighted imaging, and PET scans aid physicians in assessing whether carotid endarterectomy is appropriate—a surgery that removes plaque from the arteries that supply blood to the brain.[18]

When stroke hits, imaging tests such as CT and MRI provide rapid information about the nature and location of stroke and the extent of brain injury, allowing physicians to make well-informed judgments rapidly.[19] This information enables physicians to differentiate between ischemic stroke, involving a blockage in the arteries, and hemorrhagic stroke, which involves rupture or loss of blood. With this information, physicians can prescribe cost- and life-saving thrombolytic therapy—a drug treatment for ischemic brain attack.[20] Or they can use imaging to guide delicate surgical procedures to close ruptured arteries. Imaging also enables use of microcoil stents to correct brain

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Cardiol Mex. 2005 Jan-Mar;75(1):35-41. Also see Mowatt G, Brazzelli M, Murray A, Fraser C, Vale L. Systematic review of single photon emission computed tomography (SPECT) myocardial perfusion scintigraphy for the diagnosis and management of angina and myocardial infarction. Nucl Med Commun. 2005 Mar;26(3):217-29.

[14] See "American College of Radiology Clinical Statement on Noninvasive Cardiac Imaging," Weinreb, JC, et. al., Radiology, June 2005, Vol. 235, pp. 723-727.

[15] See "Primary Angioplasty Versus Intravenous Thrombolytic Therapy For Acute Myocardial Infarction: A Quantitative Review of 23 Randomized Trials," by Keeley EC; Boura JA; and Grines CL; in *The Lancet*, Vol 361, No 9351, Jan 4, 2003. Also see "A Comparison of Coronary Angioplasty with Fibrinolytic Therapy in Acute Myocardial Infarction," by Andersen et al, in *The New England Journal of Medicine*, Vol 349, No 8; 733-742, 2003.

[16] "Roles of Nuclear Cardiology, Cardiac Computed Tomography, and Cardiac Magnetic Resonance: Assessment of Patients with Suspected Coronary Artery Disease," Berman, DS, et. al., *Journal of Nuclear Medicine*, V 47, No 1, January 2006, pp. 74-82. Also see "How New Heart-Scanning Technology Could Save Your Life," by Christine Gorman and Alice Park, *Time*, Sept 5, 2005, pp. 58-71.

[17] See "Stroke Treatment: Time is Brain," Hill MD, and Hachinski V, *The Lancet*, 1998; 352 (suppl III) 1014. Also see "Practice Guidelines: Use of Imaging in Transient Ischemic Attacks/Acute Stroke," A Report of the Stroke Council, American Heart Association, *Stroke*, 1997; 28:1480-1497.

[18] See "Cost Effectiveness of Carotid Endarterectomy Clinical Study," Nussbaum ES, Heros RC, Erickson DL, *Neurosurgery*, 38; 237-244; 1996. Also see *The Value of Investment in Health Care: Better Care, Better Lives*, MedTap International, p. 34, 2004.

[19] "Evidence-Based Neuroimaging in Acute Ischemic Stroke," Vo DK, Lin W, Jin-Moo L, *Neuroimaging Clinics North America,* 13 (2003), 167-183.

[20] "Cost-Effectiveness of Tissue Plasminogen Activator for Acute Ischemic Stroke. NINDS rt-PA Stroke Study Group," Fagan SC, Morgenstern LB, Petitta A, Ward RE, Tilley BC, Marker JR, Levine SR, Broderick JP, Kwiatkowski TG, Frankel M, Brett TG, and Walker MD, in *Neurology*, 50, 4: 883-890.

aneurysms without open surgery, thus reducing patient hospital stays by half and allowing patients to recover months earlier.[21]

Lancet study identifies productivity gains from stroke therapy

Let me add one more small, but important point, with regard to the role of imaging in diagnosing and treating stroke. A study published this past April in *The Lancet*, one of the premier medical journals in the world, reported that three NIH studies on techniques for diagnosing and treating stroke—in which medical imaging plays a critical role in guiding physician decisions—led to a net economic benefit to society of roughly $8 billion in the 10 years following completion of the studies.[22] These are the benefits in dollar terms that arose from use of the approaches suggested in the studies, minus the total treatment costs.

These treatments—in this case, use of clot busting drugs following stroke onset and carotid endarterectomy to clear clogged arteries to the brain—would not be possible without the sophisticated imaging provided by CT, MRI, ultrasound, and other modalities. In addition, a separate study published online by *The Lancet* on July 4, 2006, added a new prospect for even greater value.[23] It found that advanced MRI is effectively able to extend the time window—which has traditionally been understood to be three hours following the onset of symptoms—during which certain patients can benefit from clot-busting drugs. This holds the potential for dramatic new savings in lives and costs.

Cancer

Medical imaging is also a primary tool in the battle against cancer. Over the past two decades, advances in medical imaging have dramatically improved cancer diagnosis and treatment.[24]

Earlier detection of breast cancer through mammography has reduced death rates in the U.S. and other countries,[25] with ultrasound and MRI aiding in diagnosis and treatment. CT, MRI, and PET scans give physicians vital information about the location and nature of cancer to aid in treatment planning. And computer-aided detection, or CAD, systems enhance the ability of mammography to detect breast cancer in its early

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[21] "Surgical and Endovascular Treatment of Unruptured Cerebral Aneurysms at University Hospitals," by Johnston SC, Dudley RA, Gress DR, and Ono L , *Neurology*, 1999; 52:1799. Also see "Endovascular and Surgical Treatment of Unruptured Cerebral Aneurysms: Comparison of Risks," by Johnston SC, Wilson CB, Halbach W, Higashida RT, Dowd CF, McDermott MW, Applebury CB, Farley TL, Gress DR, *Annals of Neurology*, 2001, May; 49(5): 682-4. Also see, "International Subarachnoid Aneurysm Trial (ISAT) of Neurosurgical Clipping Versus Endovascular Coiling in 2143 Patients with Ruptured Intracranial Aneurysms: A Randomised Comparison of Effects on Survival, Dependency, Seizures, Rebleeding, Subgroups, and Aneurysm Occlusion," Molyneux AJ, Kerr RS, Yu LM, Clarke M, Sneade M, Yarnold JA, Sandercock P, *The Lancet*, Vol. 366, Issue 9488, September 3, 2005, Pages 809-817.

[22] "Effect of a U.S. National Institute of Health Programme of Clinical Trials in Public Health and Costs," Johnston SC, et. al., The Lancet, Vol.367, pp. 1319-1327, April 22, 2006.

[23] "MRI versus CT-based Thrombolysis Treatment Within and Beyond 3-hour window after Stroke Onset," Kohrmann, M; Lancet Neurology, 2006, published online, July 4, 2006

[24]"Molecular Imaging in Cancer: Future Directions and Goals of the National Cancer Institute," Hoffman JM, Menkens AE, *Academic Radiology 2000*, Vol 7, No 10, October 2000, p.905. Also see, "Imaging in Cancer: A National Cancer Institute 'Extraordinary Opportunity,'" Hoffman, JM, *Neoplasia,* Vol. 2, No.1/2, January-April, 2000.

[25] "Effect of Screening and Adjuvant Therapy on Mortality from Breast Cancer," Berry, DA, et. al., *The New England Journal of Medicine,* October 27, 2005, pp.1784 - 1792. Also, "Effects of Chemotherapy and Hormonal Therapy for Early Breast Cancer on Recurrence and 15-year Survival: An Overview of the Randomised Trials," Early Breast Cancer Trialists' Collaborative Group (EBCTCG), *The Lancet*, Vol. 365, May 14, 2005, pp. 1687-1717.

stages.[26] Minimally invasive imaging procedures allow biopsies of breast, bone, and other tissue without open surgery, dramatically reducing infections, complications, and recovery time.[27]

Sophisticated new radiation treatment systems provide targeted radiation therapy that matches the tumor shape, but protects surrounding tissue. The result: better success rates, quicker pain relief, and fewer complications.[28]

PET and other cell-metabolism specific nuclear scans also allow physicians to identify cancer cells when they number in the hundreds of cells rather than waiting for the cancer cell doubling to the millions of cells that are needed to be seen with other modalities.

Physician Practice Guidelines Specifically Recommend Imaging

The central role that medical imaging plays in addressing disease is captured in medical practice guidelines developed by many medical specialty societies, including the American College of Radiology and the American College of Cardiology. The guidelines reflect clinical recommendations developed by the specialty physician groups themselves on how best to diagnose or treat specific medical conditions. They are based upon proven and widely accepted standards and evidence.

Recent examples of such guidelines include:

- Guidelines by the American Urological Association recommending use of ultrasound to assess prostate size or abnormalities, guide minimally invasive kidney biopsies, and examine the bladder for suspected bladder stones.[29]
- Guidelines by the American Heart Association and the American College of Cardiology recommending use of ultrasound, CT, and other imaging technologies to diagnose peripheral arterial disease.[30]
- Recommendations of the U.S. Preventive Services Task Force—the nation's pre-eminent preventive services panel—to use ultrasound screening to detect abdominal aortic aneurysms in elderly male smokers.[31] The USPSTF has long-established recommendations on the use of imaging to detect breast cancer and colorectal cancer.

Governmental bodies also frequently underscore the importance of imaging in diagnosis and treatment. Many of the national coverage decisions issued by Medicare over the past 18 months have involved medical imaging—PET scanning in particular. In 2005, the Medicare program covered PET for Alzheimer's disease and for diagnosing and

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[26] "Screening Mammograms: Interpretation with Computer-aided Detection—Prospective Evaluation," Morton, MJ, *Radiology,* Vol. 239, No. 2, pp. 375-383, May, 2006.

[27] See "Diagnosis of Primary Bone Tumors with Image-Guided Percutaneous Biopsy: Experience with 110 Tumors," by Jelinek JS, Murphey MD, Welker JA, Henshaw RM, Kransdorf MJ, Shmookler BM, Malawer MM, *Radiology* 2002; 223; 731-737.

[28] See, "High Dose Intensity Modulated Radiation Therapy for Prostate Cancer: Early Toxicity and Biochemical Outcome in 772 Patients," by Zelefsky MJ, et. al., *International Journal of Radiation Oncology, Biology, Physics*, Volume 53, No. 5; pages 1111-1116, August 2002.

[29] American Urological Association, "Guidelines for Ultrasound Utilization," accessed May 8, 2006, at http://auanet.org/about/policy/education.cfm#ultrasound.

[30] ACC/AHA Practice Guidelines for the Management of Patients with Periperal Arterial Disease (Lower Extremity, Renal, Mesenteric, and Abdominal Aortic): Executive Summary," Hirsch AT, et. al., *Circulation*, March 21, 2006, pp. 1474-1547.

[31] "Screening for Abdominal Aortic Aneurysm: A Best-Evidence Systematic Review for the U.S. Preventive Services Task Force," Fleming C, et. al. *Annals of Internal Medicine*, Feb 2005, Vol. 142, No. 3, pp. 203-211; and "Screening for Abdominal Aortic Aneurysm: Recommendation Statement, U.S. Preventive Services Task Force," *Annals of Internal Medicine*, Feb 2005, Vol. 142, No. 3, pp. 198-202.

determining the stage of esophageal, colorectal, head and neck cancer, and non-small-cell lung cancer, as well as lymphoma and malignant melanoma.[32] Medicare also agreed to provide payment for use of PET for virtually all other types of cancer if provided as part of a clinical trial or a national registry, such as the National Oncologic PET Registry.[33] Medicare coverage clears the way for use among the program's 40 million beneficiaries.

Physicians Say Imaging is Most Important Innovation

In light of the impact of imaging on the practice of medicine, Mr. Chairman, it is not surprising that it has been rated highly by physicians and medical journals alike.

A 2001 study published in the policy journal *Health Affairs* asked 225 leading general internists to rank the relative importance of 30 medical innovations in terms of their value in improving patient care.[34] These physicians, a group who do not do imaging themselves, overwhelmingly picked two imaging technologies—CT and MRI—as the most significant medical innovation. The next highest choice, a heart drug, was rated much lower. Of the top five innovations chosen by these physicians, three involved imaging: CT and MRI, image-guided balloon angioplasty, and mammography.

While this survey focused on general internists, the same broad adoption of imaging has occurred among medical specialty physicians as well. This includes oncologists, surgeons, cardiologists, internists, and emergency room physicians, among others. In March 2005 testimony, a coalition of more than 20 physician specialty groups characterized the importance of imaging in the way they practice in this way:

> "In addition to traditional diagnostics employing medical imaging, we now use imaging to guide minimally invasive treatments and to track ongoing treatment protocols through judicious use of medical imaging. We are enabled as physicians to adjust patient care plans mid-therapy to achieve the best possible outcomes. Several specialist groups intimately integrate medical imaging in the most delicate and intricate aspects of their care. The prudent use of medical imaging in the actual treatment regimen is not only excellent medicine: it also manages short- and long-term costs by minimizing wasteful and ineffective treatments."[35]

It is not surprising that *The New England Journal of Medicine* called imaging one of the top 11 innovations of the past 1,000 years—ranking it alongside such milestones as the invention of anesthesia, the discovery of the cell, the understanding of genetics, and the synthesis of antibiotics.[36]

Utilization Growth Arises from Complex Causes

Unfortunately, these broad, patient-centered changes that underlie growth in imaging are not often heard in policy discussions about utilization. As noted earlier, utilization growth is judged almost entirely on the size of the year-to-year change, not on whether the reasons behind it are sound or unsound. In fact, increase in the number of imaging procedures per patient is one of the primary metrics used to demonstrate

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[32] "Positron-Emission Tomography and Assessment of Cancer Therapy," Juweid ME, and Cheson, BD, *The New England Journal of Medicine*, Vol. 354, No. 5, Feb. 2, 2006, pp. 496-507.

[33] See http://www.cancerpetregistry.org/index.htm.

34 "Physicians' Views of the Relative Importance of Thirty Medical Innovations," Victor R. Fuchs and Harold C. Sox, Jr., *Health Affairs*, Volume 20, Number 5, September/October, 2001.

35 Williams, Testimony before the U.S. House Ways and Means Committee, March 17, 2005

36 "Looking Back on the Millennium in Medicine," the Editors, New England Journal of Medicine, Volume 342, pp. 42-49, January 6, 2000.

excessive utilization.[37] Yet it is this very metric that captures the transformation of medicine brought about by imaging—physicians use it more broadly, in more patients, for more conditions because it improves care.

In addition, it is widely accepted that financial incentives for physicians—usually in the form of self-referral—are behind the increase in imaging growth. Yet, detailed analysis of Medicare payment data done for NEMA suggests that the growth in imaging utilization has been remarkably consistent across all specialties and procedures whether or not there is an opportunity for "self-referral." In particular, the percentage of dollars spent on each of the top five imaged areas—the heart, spine, brain, extremities and abdomen—has stayed remarkably constant. This suggests that—rather than performing new studies largely for reimbursement—physicians are using better studies to answer age-old clinical questions, such as why the patient is not able to talk or move or is in pain. Notably, these imaging patterns cross all specialties—those that have the opportunity for self-referral and those for whom ordering, explaining, arranging, and tracking imaging studies done by someone else is purely an additional cost, not specifically reimbursed.

To complicate the issue of utilization further, the costs associated with increases in utilization are often overstated. In its *March 2005 Report to the Congress: Medicare Payment Policy*, the Medicare Payment Advisory Commission argued that utilization of imaging technologies was increasing out of proportion to growth in other health care services and that these increases contributed to steep cuts in physician reimbursement through a budgeting mechanism known as Medicare's Sustainable Growth Rate (SGR) formula.[38]

In fact, imaging costs have grown at about the same rate as other portions of health care spending. With regard to the SGR, imaging services grew 4.6 percent per year faster than other services that were included in the SGR mechanism. But a study done for the National Electrical Manufacturers Association found that more than half of that was due solely to a shift in imaging services from hospital outpatient departments to physician offices and other non-hospital settings. When this "site-of-service" shift—from hospital to non-hospital settings—is taken into account, imaging services grew about 2.0 percent faster than other services.[39]

A 2005 study by the Lewin Group found that when growth in imaging costs are compared to growth in all Medicare Part B services, imaging grew at roughly the same rate. From 1999-2003, the average annual growth in all Medicare Part B services across providers was 7.8 percent, while the comparable growth in imaging was 8.7 percent—only about 0.9 percentage points faster.[40]

Similarly, a study of overall hospital costs over the seven-year period of 1996-2002 at Massachusetts General Hospital found that medical imaging costs rose more slowly than overall hospital costs. The study also found that use of imaging was linked to shorter hospital stays.[41]

Utilization Growth Often Means Offsetting Savings

In this regard, Mr. Chairman, I want to underscore that, despite frequent assertions to the contrary, medical imaging reduces costs and creates new efficiencies in health

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[37] See "Report to the Congress: Medicare Payment Policy," Medicare Payment Advisory Commission, March 2005, Washington, D.C.

[38] Ibid.

[39] See "NEMA Cautions on Misinterpreting Medical Imaging Growth under SGR," National Electrical Manufacturers Association press release, April 20, 2006, accessed May 22, 2006, at http://www.nema.org/media/pr/20060420a.cfm.

[40] "Issues in the Growth of Diagnostic Imaging Services: A Case Study of Cardiac Imaging," The Lewin Group, May 3, 2005, p. 20.

[41] "Diagnostic Imaging Costs: Are They Driving up the Costs of Hospital Care?", Beinfeld MT, Gazelle GS, *Radiology*, 2005; 235:934-939.

delivery and improved productivity in patients. In these cases, greater utilization means greater savings.

- The American Heart Association journal *Stroke* reported that a "scan-all" strategy for stroke patients ultimately saved money—when compared to later, or reduced, use of CT scans for such patients—because the information from the scans led to better diagnoses that led to better outcomes and shorter hospital stays.[42] Thus, greater use of CT scans, and greater expenditures on CT scans as a result, translated into dollar savings overall.
- Physicians at Massachusetts General Hospital reported in the *American Journal of Roentgenology* that increased use of state-of-the-art CT imaging in treating facial trauma patients led to a reduction in overall imaging costs of 22 percent per patient between 1992 and 2002. The primary explanation for the findings, according to the researchers, is that CT cost less than it did 10 years earlier, did more, and increasingly substituted for X-ray examinations, which dropped by 50 percent over the period.[43]
- A study from *Radiology* found that image-guided breast biopsy costs roughly a third of what a surgical biopsy does. This minimally invasive procedure uses ultrasound or mammography images to locate a suspicious lump or nodule in the breast. It takes one-fifth the amount of time as surgical biopsy, reduces complications, and allows women to return to normal activities in half the time that it takes after open surgery. [44] In Medicare patients, use of this procedure is increasing, while use of more invasive procedures, such as surgery, is declining.

In each of these cases—and the peer-reviewed literature contains many more examples like them, for virtually all imaging modalities—the number of imaging procedures per patient increases. Yet in each case, more utilization of imaging is better, not worse, because it represents cost-savings. This underscores the point that increases in utilization do not automatically equate with inappropriate utilization.

Another complicating issue is that the budgeting and accounting systems that public and private payers use for imaging procedures fail to take into account any savings that arise from the use of that imaging. Thus, savings that offset other costs—such as substitution of minimally invasive breast biopsies for open surgery—are never reflected, while the increase in the number of imaging studies performed is tabulated. The result is a skewed picture of both imaging utilization and its costs. It is interesting to note that, in exploring the potential for Medicare payment analysis based on grouping care into all-inclusive episodes, even MedPAC acknowledges that paying for isolated pieces of care is fundamentally flawed.[45] NEMA believes that disproportionately forcing cutbacks in imaging when it can drive cost savings in other areas of care is inappropriate.

Mr. Chairman, this is our view of the forces behind utilization of imaging. To be sure, inappropriate utilization exists. It is a serious issue and we do not wish to underplay it. But as we look at the real world of health delivery, there isn't the degree of wasteful,

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[42] "Immediate Computed Tomographic Scanning of Acute Stroke is Cost-Effective and Improves Quality-of-Life," Wardlaw, JM; Seymour JC; Keir S; Lewis S, and Sandercock P, *Stroke,* November, 2004, pp. 2477-2483.

[43] Trends in the Use of CT and Radiography in the Evaluation of Facial Trauma, 1992-2002: Implications for Current Costs," Turner BG, Rhea JT, Thrall JH, Small AB, Novelline RA; *American Journal of Roentgenology*, 2004; 183: 751-754.

[44] "Core-Needle and Surgical Breast Biopsy: Comparison of Three Methods of Assessing Cost," Jeffrey H. Burkhardt and Jonathan H. Sunshine, *Radiology*, 212:181-188, 1999.

[45] "Report to Congress: Increasing the Value to Medicare," Medicare Payment Advisory Commission, June, 2006.

out-of-control utilization that many observers suggest. Instead, what is prominent is a glimpse of the power of science to offer better views inside the human body and greater insight about a patient's condition.

Continued Innovation & Patient Access Requires Informed Policies

DRA Cuts will Harm Patients, Providers, and Even Medicare

It is in this broader context of forces underlying utilization growth that that we offer these observations about the payment reductions of the DRA.

We view the DRA imaging cuts as excessive and unjustified. Given their size, these reductions will set off a chain reaction that will force many physicians to discontinue or greatly reduce the availability of imaging services. In turn, patients will find it harder to get care, will have to travel further, and will face long delays as they seek care in hospital outpatient departments. I have attached to my testimony a short policy brief summarizing our view of the DRA cuts. It was prepared by the Access to Medical Imaging Coalition, of which NEMA is a member.

To ensure continued quality care, we urge Congress to pass H.R. 5704, the Access to Medicare Imaging Act. The measure would impose a two-year delay on the cuts while the Government Accountability Office analyzes the likely impact of the cuts on Medicare beneficiaries, especially those living in rural areas. We see this as sensible health policy and prudent fiscal policy.

DRA cuts will harm Medicare beneficiaries

The Subcommittee should be aware of the breadth and significance of systemic issues that will arise from the DRA cuts.

- First, utilization will not be improved. These are budget cuts, nothing else. They affect imaging procedures without regard to whether such procedures are overused, inappropriately used, or underused.
- Second, the rate reductions bear no relationship to the real-world costs of providing imaging services. Some 80 percent of the services subject to the DRA caps will fall to levels below the office-based cost of providing the service. Many will fall to less than half of these real costs. This stands in sharp contrast to efforts by CMS, as described by Administrator Mark McClellan just last week, to ensure that payment decisions "accurately reflect the cost of providing quality care."[46]
- Third, costs are dictated by the site of care. The DRA ignores legitimate differences in the costs of providing imaging services in different settings—specifically hospital outpatient departments versus physician offices and independent imaging facilities. The legislation does this despite the fact that both Congress and Medicare have long recognized and adjusted for these differences. In fact, the DRA largely presumes that the hospital outpatient and the physician payment systems are interchangeable. They are not. They are very distinct systems with unique designs that reflect the nature of care delivered in very different settings. Rates on the physician fee schedule reflect the costs of specific procedures; hospital outpatient rates reflect the estimated cost of a bundle of different services, adjusted to reflect the expected severity of the patients who will likely need that care. Mixing these systems, especially to hunt for the lowest rates, poses threats to office-based treatments and tests that go well beyond the DRA imaging cuts themselves.
- Fourth, the DRA reductions contradict efforts in CMS and Congress to add reason and predictability to Medicare payment systems, including value-based

[46] Mark B. McClellan Remarks to InHealth, the Institute for Health Technology Studies, July 10, 2006.

purchasing proposals. It seems ironic that, at a time when CMS states that its goals for the Medicare physician payment system are to make rates "understandable, intuitive and stable," that the DRA imposes reductions that contradict this intention.[47]

- Finally, the DRA cuts may actually *increase* inappropriate utilization. The reason is the cuts are so deep they create incentives for providers to increase the number of procedures to compensate for extreme financial shortfalls.

Future diffusion of important imaging advances requires reimbursement policies that are equitable and reflective of the resources required to provide high-quality, appropriate care. The Deficit Reduction Act of 2005 reductions to imaging payments will slow – maybe greatly – the adoption of medical technologies that free patients of the older, more invasive alternatives which often require longer recoveries and hospital stays.

Policies: NEMA Should Participant in Standards-Setting for Medical Imaging

I want to add one final note in closing, Mr. Chairman. If Congress decides the development of quality or performance standards is necessary to address use of medical imaging, NEMA should play a central role.

NEMA is not only an association of imaging manufacturers, it is also a standards-setting organization. For the past 75 years, NEMA has developed hundreds of medical imaging standards for product quality, safety, and performance.

- NEMA developed a standard for ultrasound equipment enabling the physician or sonographer to monitor the acoustic output display in real time, during an ultrasound examination. This helps minimize the ultrasound exposure, while maximizing the diagnostic information that can be acquired from the exam.
- NEMA developed a performance standard and quality control guidelines for single photon emission computed tomography (SPECT) devices used in nuclear medicine, to inform clinical users whether their SPECT devices are performing properly, and therefore suitable for use with patients.
- NEMA successfully developed, and continues to update, one of the most significant standards in improving efficiency and communications in health care delivery. The Digital Information and Communications in Medicine (DICOM) standard established a common digital "language" to facilitate the interchange of information between digital imaging computer systems in medical environments.

NEMA knows the technology. We know how it is used. We understand how to set standards and maintain them. NEMA needs to be at the table.

Conclusion

Let me conclude my remarks today, Mr. Chairman, with these final thoughts.

Perhaps at its most basic level, the increased use of medical imaging reflects the human desire to know—with more certainty—what is wrong, or why something hurts, or whether a dangerous disease is present. Medical imaging devices are the ultimate digital cameras that can help answer those questions. And the ability to look inside the human body with these tools—in new ways, with more precision, and with confidence in the result—arises from advances in computing technology and, in essence, science itself. Because computer power doubles roughly every 18 months, we can expect—and hope--that these technical and technological advances to continue.

Mr. Chairman, we believe that it is short-sighted to base imaging reimbursement policy—and particularly our broader attitudes about imaging utilization—on year-over-

[47] Physician Practice Expense Proposed Rule, Federal Register, June 2006.

year growth rates overlooking these deeper realities, desires, and needs. We believe that the starting place for finding sound policies to manage imaging utilization must begin with these fundamental realities.

Attachment

Access to Medical Imaging Coalition

Protecting and Preserving Access to Quality Imaging Services for our Nation's Medicare Patients

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Imaging Cuts in Deficit Reduction Act 2005 Will Harm Patients and Physicians

ISSUE: Severe, last minute payment cuts in medical imaging in the Medicare physician fee schedule included in the Deficit Reduction Omnibus Reconciliation Act of 2005 (DRA) will lead to a wide range of adverse, unintended consequences for Medicare beneficiaries and providers.

BACKGROUND: Section 5102 of the DRA directs severe reductions in payments for many imaging services under the Physician Fee Schedule (PFS). Under this provision in the DRA, effective January 1, 2007, the payment for the technical component (e.g., equipment, non-physician personnel, supplies, and overhead) of an imaging service will be set at the Hospital Outpatient Department (HOPD) payment rate, if the PFS payment rate is higher.

CONCERNS: This change in Medicare payment policy raises a number of disturbing issues such as:

- **Rushed and Inadequate Process** – Neither Congress, nor MedPAC, nor any other public forum has held a public hearing or meeting on this proposal. This proposal has received no public comment or testimony.
- **Disproportionately Large Cuts for Imaging** – The cuts enacted for imaging by the DRA comprise roughly one-third of the total Medicare savings in the bill. Yet imaging only comprises roughly one-tenth of Medicare spending. Examples of these cuts include:
  - **Ultrasound -** Reimbursement for ultrasound guidance procedures, performed as part of a minimally invasive biopsy for the diagnosis of breast cancer (a biopsy method which saved the Medicare program $88 million from 2001 – 2003), would be reduced by 35 percent.
  - **PET / Nuclear Medicine -** Reimbursement for PET/CT exams used to diagnose cancerous tumors and determine the effectiveness of cancer treatment would be reduced by upwards of 50 percent (an unprecedented cut for a new technology whose HCPCS code was just provided by CMS in April 2005).
  - **DEXA -** Reimbursement for bone densitometry studies necessary for the diagnosis of women at risk for osteoporosis (a recently enacted Medicare screening benefit) would be reduced by over 40%.
  - **MRI -** Reimbursement for MR angiography of the head used to detect the location of aneurysms would be reduced by 42%.
- **A Failure to Recognize the Fundamental Differences between the costs associated with practicing medicine in a physician's office, and practicing medicine in a hospital outpatient department -** The different payment formulas for each site of service are specifically designed by Congress to take into account the

unique differences and costs of providing care in each setting. Linking reimbursement under the PFS system to the HOPD system ignores real-world costs in personnel, rent, and supplies that physicians in non-hospital settings must deal with daily.

- **Limiting Beneficiary Access to Critical Imaging Services** – These cuts have the very strong potential to drive imaging from the physician office and free-standing facilities back into hospital outpatient departments, thus limiting Medicare beneficiaries' access to nearby imaging services that allow for more timely diagnosis and initiation of treatment.
- **Longer Wait Times for Medicare Patients** - On average, patients already wait 10 days to two weeks for non-urgent imaging services in the hospital outpatient department. Reduced access to imaging services in the physician's office and in free-standing imaging centers could increase these wait times dramatically.
- **Reduced Access For Medicare Patients in Rural Areas** - Beneficiaries may be forced to drive long distances for needed imaging services if providers reduce or eliminate imaging locally. Also physicians may choose not to invest in telemedicine equipment that allows specialists at distant locations to help interpret a patient's scan —again harming rural access.

SOLUTION: Please support HR 5704 to delay implementation of DRA Sec. 5102 for two years, while the GAO conducts a thorough study of the impact on patient access and services.

MR. DEAL. Well, thank you all. A very interesting panel. I think it demonstrates how difficult it is to get our hands around this issue, because you all are coming at it from somewhat different points of view, perhaps, at least in part.

Let me see if I can find some indication of where we are on some of the issues that have surfaced. One of the issues that surfaced, obviously, is the question of standards, whether they should be federally imposed standards, and whether there should be standards that maybe, as Dr. Douglas suggested, may be incorporated into pay-for-performance type of approach to it. I will go down the line and I will start with Dr. Douglas, how many of you feel that there is a need for Federal standards to be adopted in the imaging area?

DR. DOUGLAS. I think there's a need for Federal standards, provided that they respect specialty-specific knowledge. I don't think any of you, God forbid you had a heart attack, would want anybody but a cardiologist taking care of you.

MR. DEAL. I am going to come back to that next.

Dr. Van Moore.

DR. VAN MOORE. Clearly, I think we would advocate because of the fact that there is a lack of uniformity. There can be a relatively disparate lack of uniformity in the way the States are handling the IDTF issue--

MR. DEAL. So you would be a yes?

DR. VAN MOORE. --for Federal standards.

MR. DEAL. Yes.

MR. DONAHUE. I would be for it, Chairman Deal. I believe that Federal standards imposed that consider the nuances in specialty and modalities would be very effective in improving the quality of care.

MR. DEAL. All right.

DR. LAUBE. I would be against, as our imaging capabilities are primarily those of ultrasound, which I think we handle on a voluntary basis through various--

MR. DEAL. You would be opposed to Federal standards on ultrasound, even?

DR. LAUBE. Yes.

MR. DEAL. Okay.

Dr. Griffeth.

DR. GRIFFETH. Speaking strictly personally, I have general support for standards. I think it is a very delicate issue that should be approached primarily through education rather than any sort of punitive system, and I think this, once again, raises the question of how much we are going to single out imaging. Are we going to adopt standards for imaging that are different or higher than standards for other practices of medicine, say surgery or psychiatry? I think it is a very difficult issue.

MR. DEAL. Mr. May?

MR. MAY. We advocate standards for non-physician personnel operating medical imaging equipment.

MR. DEAL. Mr. Baumgartner.

MR. BAUMGARTNER. We would agree with those recommendations as well as the equipment standards for providers. There is a lack of consistency amongst the various administration regions on standards today.

MR. DEAL. Dr. Rucker.

DR. RUCKER. We think there are already quite a few standards in many different areas. Many of these sort of standards are sort of thinly disguised, I think, turf battles, and don't lead to cost-competitive and cost-effective medical care. Certainly in looking at the MedPAC written testimony, it doesn't look like any of the studies that were cited actually showed actual harm to patients.

MR. DEAL. All right.

Let us go back and dissect that a little bit. That is a good word to use in medical terms.

DR. DOUGLAS. We try to avoid the point until we get to dissecting.

MR. DEAL. Dr. Douglas's point is that it needs to be specialty-specific. Now, I understand that, and I tend to agree with that. I think it maybe can go further and that is whether or not it also needs to be test-specific, instrument specific, whatever test you are using, and the examples we have already heard here are, let us see. We had, of course,

ultrasound, whether or not that needs to be carved out as an area that is dealt with as a specialized area. We have also heard Dr. Griffeth say PET scanning needs to be considered, perhaps, in a little different arena and is already regulated in terms of usage.

So let me ask this question then. Are there certain types of imaging procedures that should be carved out and certified, based on the specialty of the medical practice of the person so that someone who may be carved out for ultrasound may not be carved out for certification for CTs or PET scans or whatever else? Is there any common sense to an approach of that nature? Dr. Douglas.

DR. DOUGLAS. I think there are, if you can envision what it takes to do quality imaging. It starts with picking the right test for the right patient, and that is obviously very specific to the patient and to the test. The next thing that happens is you acquire images, you acquire pictures very specific to the test. Things that might make a good CT scan might make a lousy ultrasound, and vice versa. But there are specific things, specific imaging protocols, completeness of the study, that would judge quality that are generic, but how the particular measure might be for each modality.

You want the interpretation to be done by a skilled observer who knows what they are doing, has been trained to do it, and meets standards that exist for those things, and you want the reporting to also meet quality measures. Then, of course, that gets translated into altered care for the patient and hopefully improved outcomes.

MR. DEAL. Unfortunately my time has run out before I get complete answers to my questions, so I will yield to Mr. Pallone.

MR. PALLONE. Thank you, Mr. Chairman.

I wanted initially to ask Mr. Baumgartner a question.

It seems there are several levels of technical skill that are required, depending upon the complexity of both the patient's individual circumstances and the imaging procedure being performed. For example, some services like an OB ultrasound seem possible and even preferable to be performed at a physician's office, but I am sure there are other examples of more complex procedures that should be referred to an imaging specialist. I just wanted to ask what guidance you can give us to assure we are meeting the needs of the patients and physicians while also assuring the highest possible quality with any standards.

MR. BAUMGARTNER. Sure, and I would agree with that statement, Congressman.

We are not advocating that certain physicians not be allowed to perform those procedures. It is absolutely necessary, but I think you have heard from Mr. Donahue and others that there is some over-utilization going on. NCQDIS is supporting quality standards, and we

think that should be based by equipment type, regardless of who is providing that procedure. So whether it is an orthopedist or a radiologist, we think the standard should be the same.

MR. PALLONE. Okay, thank you.

Then I wanted to ask Dr. Laube, on the first panel we heard a lot about standards for imaging services; however, I know that ACOG--is that right, ACOG?

DR. LAUBE. Yes.

MR. PALLONE. Has tried very hard to educate its members about the appropriate use of imaging services. And when you discussed what ACOG is doing in this area and the model programs it uses to help train its members, when to order an ultrasound and when an ultrasound is not clinically indicated?

DR. LAUBE. Yes. We have a variety of ways that we educate, beginning in our postgraduate training years, that is the residency, beginning year one through year four on a progressively more complex basis. For the graduate of a residency program, ACOG offers a number of different types of CME courses for practicing physicians to gain CME in this area. Our specialty societies, the cancer group, the GYN cancer group and the reproductive endocrinologists and infertility doctors are all working with AIUM, the American Institute of Ultrasound in Medicine, to develop various types of, for lack of better word, credentialing procedures or accreditation procedures.

So education occurs at a general level through residency for our general OB/GYNs on a postgraduate basis, and for our subspecialists on a subspecialty basis.

MR. PALLONE. Okay, thanks again.

And then last, I had a couple of things for Mr. Donahue.

I heard concerns that many of the programs that are put in place to reduce the utilization of radiology services, such as preauthorization of services, are by design broad brush and may simply create additional bureaucracy for tests that are appropriately ordered. So wouldn't it be more effective to simply identify the providers whose ordering patterns are irregular compared to other similarly situated providers and work with them to bring their practices into alignment? By implementing across the board programs that affect all providers, doesn't that cause providers whose practices are actually doing the right thing to incur unneeded administrative costs?

MR. DONAHUE. That is a very good question, Congressman Pallone. I think firstly, you have to take a very specific causal factor look at what is driving utilization in any region of the country. What we endeavor to do is exactly what you described. We use the data, the historical claims data, the clinical evidence that we have to design a radiology program

that fits the community. One of the things that we have learned over the last 10 years, ordering patterns, quality concerns, safety concerns, and the capacity and network and access concerns are unique in all of these 50 States.

So our programs, in fact, do very much address the uniqueness of specialty ordering. As an example, we have a Board-certified radiologist who will have peer-to-peer discussions with radiologists, Board-certified cardiologists who will dialogue on the clinical merits of a case when cardiologists interact with us, Board-certified gynecologists who will interact with us on OB/GYN issues. So I agree with your concern, a broad brush approach is not the most effective was to take this on, but programs like ours, radiology benefit management programs that address the uniqueness of the community and the specialties do work, do add value, and we feel could unlock billions of dollars in savings in the Medicare Advantage, in the Medicaid programs for this country.

MR. PALLONE. Can I just ask a brief follow-up to him?

MedPAC recommended to create a profiling mechanism to allow physicians to compare their use of imaging with their colleagues. Is that something that you agree with, just quickly?

MR. DONAHUE. I think physician profiling and peer assessment on a confidential basis that MedPAC recommended are very effective.

MR. PALLONE. Okay, thank you.

MR. DEAL. Dr. Norwood.

MR. NORWOOD. Thank you, Mr. Chairman. I just want to point out at the beginning, I would like to associate myself with the remarks of all of this panel, except Mr. May and Dr. Donahue. Mr. May, I don't have any problems with what you were saying. That is not what this hearing is about, and perhaps we will deal with that at another hearing. Whether we have Federal standards or not makes me extremely nervous, because I never know who is going to write them. Mr. Donahue's outfit may write them, and that scares me to death. I would much rather have physicians writing these standards who I believe in and can trust.

The first panel we had today proves to me without a doubt that we need to pass Mr. Pitts's bill. Perhaps we need to go further than that. Perhaps we need to not put this off for a year, but strike it from the record because MedPAC and CMS have no clue what they are talking about yet. They proved that all morning; they couldn't answer questions. They had not done thorough studies, and we need to do what you are doing now, Mr. Chairman, as the beginning process of trying to learn what is going on so we actually--if we do need to legislate, we can do so from a point of knowledge rather than speculation.

I hear even today some say well, there must be some over-utilization going on. Well, maybe there is. I would like somebody to come along

and say, and here is why I am saying that. We have the proof of that. We know nationally why there is over-utilization, because it is always sort of well, we sort of assume it. Surely, there are bad guys--as many bad docs as there congressmen, so most likely there is over-utilization going on. You can't prove statements like that unless you are there with the patient, and these Board-certified cardiologists that are 10,000 miles away from the actual treating physician can't diagnose over the phone very well. They are often wrong. I have been there, done that, and know a lot of people who have done the same thing, so you can't depend on stuff like that.

So Mr. Chairman, rather than answering questions, I would urge the Commerce Committee to get rid of this language, and let us do, unlike the Ways and Means Committee did, let us study this issue and try to come up with some sensible reforms.

With that, I would like the panel to finish answering the Chairman's question that he asked earlier.

MR. DEAL. Thank you for that, and if you would yield, I would like to modify that just a little bit and clarify what I am getting at.

I think we need to understand whether or not there can be certain types of test that are so uniquely aligned with certain specialties that they should be treated differently for purposes of setting standards of usage, certification of equipment perhaps. That was really the base of the question. I appreciate your allowing them to answer that, and I guess we got to Dr. Moore.

DR. VAN MOORE. Thank you, Chairman Deal.

It is our belief that if you look at a specific imaging procedure, regardless of what it is, whether it is an MR of the knee, a CT of the heart, that the physicians that are involved in the interpretation and evaluation of the exam should, regardless of specialty, have the same criteria in quality in terms of the training that they have, the requirements that they have in terms of providing the reports and rendering an opinion on that examination. I think not to have that, to have different specialties have different standards or different ways, patients will not benefit from it. So we would advocate for uniform standards for individuals that are providing a study regardless of the specialty.

MR. DONAHUE. Thank you, Mr. Chairman. I would like to make an attempt to draw consensus from the group, because I think there is one area of standards that we would all agree on, and that is on the safety of imaging equipment and the rendering of imaging as it relates to the patient, and the very concerning issue of radiation exposure. I am sure the panel is familiar with the National Academy of Sciences' study that was conducted in 2005 that indicated as the intensity of particularly CT equipment increases the level of radiation exposure to a patient, there is a

clarion call to monitor radiation dosages for patients and to ensure that there are standards on the equipment to make sure that it doesn't erroneously emit radiation that could further provoke carcinogenic effects.

MR. DEAL. And that is not being done in all instances now?

MR. DONAHUE. In all instances, Mr. Chairman, it is not, and there are a number of clinical studies that are taking place. And this is another important factor I think all of the various distinguished members of the panel would agree on. As it relates to your primary focus on the question, I believe there are probably categories of specialists who are better equipped, in terms of their clinical training and experience, to ordering exams, but I wouldn't go so far as to say that specialty A only has the capacity to perform an exam.

I will give you just one brief example, lumbar spine MRIs. There are radiologists, there are cardiologists, there are specialty trained internists who focus on sports medicine who all have terrific credentials and experience to order this. One may not. There are some specialties that don't examine the lumbar spine that we would want to assure have no opportunity to order an exam like this.

MR. DEAL. I have more than exhausted Mr. Norwood's time.

Mr. Pickering.

MR. PICKERING. Thank you, Mr. Chairman, and just as an effort to try to find both the consensus and clarification, as we talk about standards there are different forms of standards in different areas, but is there consensus among the panel that there should be standards as far as to the education and the credentials of any group performing imaging services? Is there a consensus on that front? I would like to ask the panel if there is agreement or any disagreement, and if so, what are those areas of disagreement?

MR. DEAL. Could I ask for clarification?

MR. PICKERING. Yes.

MR. DEAL. In light of your bill, it relates to the technologists and the equipment. Is that where you are focusing it?

MR. PICKERING. The focus is there, but it would say for physicians or technologists, or anybody who is providing the service. It would make the distinction but it would have a minimal Federal standard that then the States would implement in order to be eligible for the reimbursements.

DR. DOUGLAS. We believe that imaging is a whole process, and that education of the technologist or stenographer or whoever, as well as the physician, is critically important. We think that the standards for each laboratory or each type of test have been generated by multi-specialty groups and need to do so on a local level with people who understand

those tests best. That is not necessarily cardiology, it is not necessarily radiology, but we need to respect the standards that are out there and work with them.

ACC has been part of the Intersocietal Accreditation Commission for ultrasound, nuclear, MRI, CT vascular laboratories and we feel it is a model program.

MR. PICKERING. Dr. Douglas, would you say that additional Federal standards on education, would that be helpful, or are you saying that what is already out there as far as different specialty groups, this is currently sufficient?

DR. DOUGLAS. I think an additional standard might be duplicative. What would be better and what the ACC supports is mandatory accreditation for reimbursement, specialty-specific generated accreditation. It could be ACR, it could be cardiologist groups, but mandatory for reimbursement. But there is no need for additional standards beyond that.

MR. PICKERING. And just for clarification, the bill that I introduced does not include physicians. We allow you all as you have said to go ahead and do your specialty-specific accreditation.

DR. DOUGLAS. Lab accreditation includes education and standards for stenographers and technicians as well, and not necessarily under radiology.

DR. VAN MOORE. I think there are two aspects of the question that you have. One is as Dr. Douglas talks about, the accreditation programs and the American College has got accreditation programs which looks at the facilities, the equipment, the quality of the images, the quality training of the physicians, the quality of training of the technologists to ensure those all meet certain standards. If you look at also then the MQSA, that clearly that if you are going to do mammography and if you are going to be involved in the care of those patients you need to have certain minimum requirements and continuing medical education specific to the area that you are rendering the high level of expertise in. So that if you combine those with respect to accreditation, looking at some of the components that have made MQSA so successful and also look at the requirements of IDTFs and how if you fold all those into a complete package, we believe that that will be a solution where utilization in and of itself, because there will be fewer exams that are ordered or requested or performed that are less appropriate, that in and of itself will reduce utilization of procedures, and by doing that will save the money that you are looking to save with respect to the offset, as I said in my initial comments.

MR. DONAHUE. I would add, Congressman, that this is such a dynamic and evolving technology that the notion of continuing education

standards that keep up with the evolution of this technology greatly appeal to me. I agree with Dr. Douglas. There are numerous folks, physicians, and ultrasound techs and rad techs and others who are involved with this who need to keep up with the nuances and the emerging opportunity to use this technology in the most effective way.

DR. LAUBE. Yes, I think I support standards in education, obviously, as I am an educator, and we have what in effect is a Federal or nationwide standards, and that is called Board certification. So we already promote the notion of standards that are applicable to all the Nation's 50,000 obstetricians, gynecologists, as well as our efforts at continuing medical education. In this regard for us, of course, as I have mentioned, it is ultrasound, but yes, I certainly support standards. That is what we are all about. But I think we can go about it through our own expert specialty societies.

MR. DEAL. I am going to ask indulgence of the committee. This end never gets to answer anything because we run out of time. Unless somebody objects, let us let that end of the panel answer that question. Dr. Griffeth, you may proceed.

DR. GRIFFETH. The scope of my comments is limited to positron emission tomography, means that I have a little less to say probably about this since PET imaging has come along later than the other types of imaging. We are talking about even though it was invented back in the mid-'70s, it has been clinically adopted much more slowly, predominantly because it was the later of the advanced medical imaging technologies to come along which provided the opportunity for CMS to regulate or over-regulate its utilization and has provided opportunities for other State regulatory agencies to impose those sorts of criteria regarding who can do PET imaging. My guess is that a Federal regulation regarding the interpretation of PET imaging is likely not to be any more strict than what is already involved in most State regulations regarding performance and interpretation of tests utilizing radioactive materials.

MR. MAY. Standards of quality will affect the overall quality, safety, and cost of imaging services. Dr. Norwood asked why we were here, and I think the answer is because quality standards will restore money back to Medicare, if the tests are--

MR. PICKERING. Mr. May, could you pull the microphone a little bit closer?

MR. MAY. I am sorry. Thank you.

MR. PICKERING. No trouble.

MR. MAY. The standards will affect overall quality, safety, and cost of providing medical imaging services, and unfortunately, the States haven't done their job. There was a bill passed in 1981 that addressed this issue, and it set forth discretionary standards for the States. Only 41

States now regulate radiographers. Those are people that administer X-rays. Only 30 States regulate radiation therapists. Those are people that use medical imaging or radiation to treat cancer, and only 25 States regulate nuclear medicine technology. These are people that use radio pharmaceuticals to detect imaging.

So unfortunately, the States have not done their job. We do need standards that may vary from modality to modality, but the outcome, the quality standards should be the same in terms of good patient care.

MR. BAUMGARTNER. Congressman, we would support minimum education standards, and if the States would like to add to that, they could feel free to do that still, but I think some minimum education standards for technologists is appropriate.

DR. RUCKER. I think physicians order imaging studies to ask and answer clinical questions, and I think those questions vary widely. For example, I might ask Dr. Douglas, who as it turns out was my resident several years ago, for an elaborate cardiac echo on valves. If I am taking care of somebody in cardiac arrest, I might just look quickly at that heart to see whether the heart is beating or not. So you know, both are echo of the heart, but very, very different and probably need different billing codes. So I think there are some very different specialty-specific uses of these imaging studies.

MR. DEAL. We are going to have to try to hurry if we get these questions in.

Mr. Pitts, you are recognized.

MR. PITTS. Thank you. I will start down at the other end, Dr. Rucker.

DR. RUCKER. Thank you.

MR. PITTS. In light of the fact that MedPAC raises doubts about the value of imaging and, in particular, bases much of that concern on the rapid growth in imaging utilization, are you aware of any peer-reviewed literature that sheds additional light on this point?

DR. RUCKER. There is a tremendous amount of peer-reviewed literature looking at the benefits of imaging, literally in the tens of thousands of articles. For folks who are interested in that in any specific specialty, the National Library of Medicine has a wonderful website, pubmed.gov. Just type in the name of the imaging study, the disease, and you will get a flavor of the simply stunning amount of scientific literature that backs up many of these practices.

MR. PITTS. I don't know if you passed out this booklet to the members or not, but this seems to tell the story of imaging. Can you comment on what this illustrates for the members? I don't know if they have it or not.

DR. RUCKER. Yes, and we are happy to provide any member who may not have gotten a copy of it. It is a book of images from 64 sliced CT scans. It shows, I think, the tremendous technology. It shows the stunning clarity of these computer-generated images, and I think it highlights, Representative Pitts, the rapidity of the change which also gets to whether standards could begin to evolve anywhere near as rapidly as the imaging technology that the manufacturers are providing is changing. We suspect that is not the case.

MR. PITTS. Dr. Griffeth, why is it so important for such advanced imaging to be available out in the community rather than having patients get their imaging done at large medical centers and just having the treatments done in the communities?

DR. GRIFFETH. The simple fact is that most of us believe that the most effective cancer care is integrated cancer care, and there has been a huge push over the past couple of decades, both from the provider community whose primary issue is the delivery of this better patient care, and from the payer's standpoint, who as far as I know, the vast majority of their data showed that care is more economic out in the community than it is at major medical centers. I think the value of having the imaging close by for patient convenience--we are talking about cancer patients who are very ill who may have, unfortunately, as part of the discussion today, repetitive imaging studies who have to have those imaging studies integrated very closely into their patient care. It is not a matter of being able to often get back a report of a study and be able to utilize that. There generally is a considerable benefit from one-to-one interaction between the imager and the physician treating the patient.

So for all of those reasons, not to mention the fact that so much of our patient base in oncology is out in rural areas that are pretty remote from major medical centers that the simple added burden on a patient population that need to know more added burdens I think would be the crux of my issue.

MR. PITTS. Dr. Douglas, in your statement you state that appropriateness criteria will weed out inappropriate utilization, improve imaging quality, and facilitate reimbursement in a performance-based system. To what extent are these criteria followed, and what, if anything, is done to ensure compliance? Is it voluntary? Are physicians penalized for not following them? How do the guidelines work?

DR. DOUGLAS. At this point, the guidelines have just been published a few months ago and we are in the process of implementing them. We work very closely with the medical directors of payers and have our fifth annual Medical Directors Institute coming up this fall and hope to learn from them how they are using these criteria to better understand imaging amongst their beneficiaries.

MR. PITTS. And Dr. Griffeth, you mentioned in your statement a Trailblazer, Dr. Burkin, and you support his approach to establishing appropriate frequency guidelines for imaging. Can you elaborate a little bit on that?

DR. GRIFFETH. Dr. Burkin is one of the medical directors for Trailblazer Healthcare, one of CMS's carriers, and CMS as part of their, as I mentioned before, tight regulation of eligibility requirements for patients having PET study has also given the carriers leeway to establish these frequency guidelines, particularly for follow-up studies performed to determine how a patient's treatment has worked or whether a patient's disease has recurred. Several payers have addressed this as a possible area of over-utilization. Dr. Burkin has, I think, taken a very rational approach that is still in evolution of consulting very closely with folks from both the imaging side and from the treatment side to determine what appropriate clinical guidelines might be for those frequency limitations.

MR. DEAL. Dr. Burgess, you are recognized for questions.

MR. BURGESS. Thank you, Mr. Chairman.

Dr. Griffeth, we tried to get the information from MedPAC and CMS, and it was difficult to do, but do you have an opinion as to the value of imaging in regards to the Medicare system? Is this something that costs or pays?

DR. GRIFFETH. Obviously, I wouldn't be sitting here if I didn't think it paid, but you know, the fact of the matter is while we have spent a lot of time talking about cost effectiveness, and I am here primarily as a patient advocate, I would be here talking to you and saying the same thing even if I did think that PET imaging in specific was costing the budget money, because I believe that this is appropriate patient care.

Having said that, yes, I believe we are saving money on a daily basis. I do believe that there is opportunity for over-utilization. In my experience, if there is considerable over-utilization, it overwhelmingly is coming from physicians who might be being overly cautious with taking care of their patients and they have been convinced of the value of advanced medical imaging to answer questions they couldn't have answered before.

So my personal opinion is that yes, we are certainly saving money. Perhaps with some refinement of utilization guidelines and education, we could save a bit more.

MR. BURGESS. On the--and I apologize if you have already answered this question. I got distracted by this very colorful booklet that was handed to me, Dr. Rucker. The issue came up, I think Mr. Baumgartner brought up the issue about a ban on self-referral. How

would that affect a group such as yours, U.S. Oncology, and your ability to interact with physicians in your own group?

DR. GRIFFETH. Well, I am not sure.

MR. BURGESS. I was actually addressing it to you, Dr. Griffeth.

DR. GRIFFETH. I need to make clear, I am not a member of U.S. Oncology. U.S. Oncology reimburses my department for part of my time to help them determine appropriate utilization of PET and their oncology patients. I must say that our interaction with the oncologists is, as I alluded to earlier, crucial in the care of the patient. The two-way interaction, educating them both in terms of the value and the limitations with PET, and them educating us regarding what sort of patient care decisions they need to make is invaluable.

MR. BURGESS. Dr. Laube--and I guess our time is drawing to a close, Mr. Chairman. I get the impression from you that ultrasound in OB/GYN is different than perhaps other imaging technologies in other specialties. Is that a fair statement?

DR. LAUBE. Yes, different in the sense that we need to have it day-to-day in our clinical practice onsite in real time. And so I think we are considerably different from the others. We don't want to do MRIs or CTs for sure, and we don't want to learn how to do them.

MR. BURGESS. The issue was brought up on standards for education. In your testimony, you have certainly drawn--posed a question, I think in my mind at least, and that is as the residency training for the average OB/GYN resident in ultrasound has increased, the training for the average radiology resident may have reduced in OB/GYN because of the lack of clinical material which is being, of course, attended to appropriately by the OB/GYN resident. Do you see that as an issue for us going forward?

DR. LAUBE. I personally don't. I think that is an appropriate shift, from my perspective, of course, for the reasons I just mentioned. We need to have our tool day-to-day, 24/7, 365, and I think that--

MR. BURGESS. Let me just interrupt briefly. When it comes then to the issue of accreditation, is an OB/GYN residency going to be an acceptable credential for someone who is to be accredited in ultrasound, and conversely, is a radiology residency going to be an acceptable credential in the same field?

DR. LAUBE. I don't think for us that the radiologist can or should accredit us. I think we should take care of ourselves because that is what we do, and as you pointed out, with our experience going vastly up in the last 10 years, theirs has gone dramatically down in our field.

MR. BURGESS. Yes, sir. Thank you, Mr. Chairman.

MR. DEAL. Thank you.

Ms. Myrick.

MS. MYRICK. Well, I know we are out of time, so in interest of that, I know everybody has to go vote. I will just thank you all and any questions I have I will get to you individually. Thanks.

MR. DEAL. Let me also thank all of you, and I apologize that we are having to rush out, but we are just about out of time on the floor for a vote that has been going on. Very interesting panel, very interesting discussions. If you wish to supplement any of your answers or provide additional information, we would encourage you to do so.

Thank you all for your presence today. With that, this hearing is adjourned.

[Whereupon, at 1:45 p.m., the subcommittee was adjourned.]

RESPONSE FOR THE RECORD OF HERB KUHN, DIRECTOR, CENTER FOR MEDICARE MANAGEMENT, CENTERS FOR MEDICARE & MEDICAID SERVICES, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

Answers to Questions for the Record Submitted to
Herb Kuhn, Director, Center for Medicare Management
Hearing on Medical Imaging
Energy and Commerce Health Subcommittee
Tuesday, July 18, 2006

The Honorable Charlie Norwood

1. What has been the effect of grouping together very different imaging techniques under the title "diagnostic imaging" for payment? Would it be better to label and address each technique separately?

A. The Berenson-Eggers classification system is a widely used system to group physicians' service codes into clinical categories. We used two digit Berenson-Eggers categories to present data on imaging and other services in our April letter to MedPAC. We included those data in my statement. Any grouping system and presentation of data can be more aggregated or more disaggregated. Different levels of aggregation or disaggregation have advantages and disadvantages. One level of aggregation isn't necessarily preferable to a different level of aggregation.

2. Are the changes in the DRA intended to limit unnecessary utilization?

A. Medicare spending for imaging services doubled over 5 years. As my testimony indicated, there is huge geographic variation in spending for imaging services. In fact MedPAC found more geographic variation in imaging services than other physicians' services. Huge growth and wide variation raise questions about the appropriateness of services and whether all imaging is medically necessary. The DRA provision creates a level playing field between physicians' offices and outpatients departments (OPD) for services whether the payment rate is greater in a physician's office than an OPD. To the extent that imaging utilization is driven by financial incentives, a more level playing field would create incentives to eliminate unnecessary utilization.

3. I am deeply concerned about the potential impacts of the imaging reductions in the DRA. Have the potential consequences been examined? Is it possible these cuts will affect patient access, leading to late diagnosis and greater costs?

A. The DRA provision caps the physician fee schedule at the payment rate for the hospital outpatient department (OPD). Since the imaging services have been furnished in OPDs without access issues, one might expect that the same access in OPDs would continue to be available. In the context of rapid growth and significant geographic variation, it is unclear what would happen to patient access.

4. Many times treating a patient requires using more than one imaging technique. Do you consider volume on a per patient basis or do you count each encounter separately?

A. Medicare's payment system for imaging treats each service separately except for the multiple imaging provision. Under such policy, Medicare pays 100 percent for the first service and reduces payment by 25 for additional imaging services furnished on contiguous body parts during the same session.

5. Now I have the same concerns with Pay for Performance. Are you only concerned that a doctor performs two procedures when you say one is necessary? What if, in their or my, medical opinion, obtaining an additional scan is vital to ensuring proper care? Who is CMS to determine this without individual patient level data or input from medical organizations and specialties?

A. Pay for performance does not involve CMS saying how many procedures are necessary. Under pay for performance, physicians will continue to make the best clinical judgments for their patients. The quality measures are being developed by the medical profession. Measures of resource use would give physicians comparative information on a confidential basis so they could see how they compare to like physicians furnishing like services.

5. How much of the growth in imaging utilization is a result of the increasing amount of women receiving mammograms—which catch cancer in its least costly stage? Also, how much of this growth is a result of MRI or CT use to identify the nature and location of strokes?

A. We do not have information on either of these points.

6. How does CMS quantify the value of imaging? That is, how is imaging's cost effectiveness valued? Is better treatment or a decreased need for surgery recognized? What about cost shifting away from the hospital?

A. CMS does not quantify the value of imaging. CMS does not value the cost effectiveness of imaging services. Resource use measures would cover all the services furnished or ordered by a physician for an episode of care. Thus a physician who better treated a patient and avoided a hospitalization would show up more favorably than an physician who didn't so treat a patient.

The Honorable Lois Capps

1. I'm very concerned that if you apply these cuts to procedures involving cancer patients, they will have a hard time maintaining access to needed services. The fastest growing segment of the population is individuals over the age of 85. With this aging population, there is significant growth in the number of cancer patients. Don't you think we should be facilitating treatment options for these patients instead of in any way hindering their access to needed treatments?

A. Radiation oncology services are not imaging services. Thus, radiation oncology services would not be subject to the DRA imaging provision.

RESPONSE FOR THE RECORD OF GLENN M. HACKBARTH, CHAIRMAN, MEDICARE PAYMENT ADVISORY COMMISSION

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Mark E. Miller, Ph.D., Executive Director

August 17, 2006

The Honorable Charlie Norwood
Subcommittee on Health
House Committee on Energy and Commerce
2125 Rayburn House Office Building
Washington, DC 20515

Re: Imaging services in Medicare

Dear Congressman Norwood:

This letter is in response to the questions you sent us on August 2nd. Answers to your questions are as follows:

1. In its June 2005 report to Congress, MedPAC concluded that CMS' current equipment use and interest rate assumptions were leading to overpayment of imaging services under the Physician's Fee Schedule. I am concerned regarding the sample surveyed that enabled MedPAC to make this conclusion. For instance, were any physicians from clinical specialties involved in direct patient care, such as surgery, OB/gyn, urology included in the sample?

In MedPAC's June 2006 Report to the Congress, we examined two key assumptions used by CMS to calculate physician practice expense payment rates: how frequently providers use equipment and the cost of capital (interest rate) to purchase equipment. We found evidence that these assumptions may no longer be accurate and suggested that CMS revisit them, but we did not make a formal recommendation. The agency assumes that imaging machines (and all other types of equipment) are used 50 percent of the time that a practice is open for business, which may be too low. We surveyed imaging providers in six markets and found that they were using MRI and CT machines much more frequently (the mean use rate for MRI machines was 91 percent and CT machines was 73 percent), which should lead to lower costs per use. (As machines are used more frequently, the cost per service declines.) The survey included 133 independent diagnostic testing facilities and physician offices in six markets that performed MRI or CT studies. Each provider in these six markets that billed Medicare for MRI or CT services in 2003 had an equal chance of being selected for the sample. Several physician specialties were represented in the sample, including radiology, orthopedic surgery, radiation oncology, and neurology.

CMS assumes that providers pay an interest rate of 11 percent per year when purchasing equipment, but more recent data from the Federal Reserve Board suggest that a lower interest rate may be more appropriate (a lower interest rate would reduce the estimated cost of equipment). The Board collects quarterly information on commercial and industrial loans made by commercial banks to different types of borrowers. Based on the Federal Reserve surveys conducted during the last 5 years (from the second quarter of 2001 to the first quarter of 2006), loans of more than one year had average annual interest rates over the last 5 years that ranged from 5.3 percent to 6.0 percent, depending on the risk of the loan. MRI and CT machines have an estimated useful life of 5 years.

2. Ultrasound guided breast biopsies are often a favored alternative to open surgical biopsies for a number of reasons. However, these biopsies require two ultrasounds to be performed. Would MedPAC consider this a rightful use of ultrasounds imaging services?

MedPAC does not perform research on the appropriateness of specific clinical decisions.

3. MedPAC raises doubts about the value of imaging, based largely upon the rapid growth of the procedures. Are you aware of any peer-reviewed literature that sheds some additional light on this argument?

We recognize that imaging technology can improve patient outcomes by allowing greater precision in diagnosing and treating patients and, in some cases, substituting for more invasive diagnostic techniques. We also recognize that it is very difficult to distinguish desirable from undesirable increases in imaging volume and appropriate use from inappropriate use. Because great care must be exercised in this area, we did not recommend a sweeping, across-the-board reduction in imaging payments. Instead, we recommended the following targeted changes:

- the Secretary of HHS should improve Medicare's coding edits for imaging studies,
- the Congress should direct the Secretary to set quality standards for all providers who bill Medicare for performing and interpreting diagnostic imaging studies,
- the Secretary should measure physicians' use of services (including imaging) so that physicians can compare their practice patterns with those of their peers, and
- the Secretary should strengthen the rules that limit physicians' financial incentive to order more imaging services.

Peer-reviewed studies have raised questions about whether all imaging services add value at the population level and whether imaging substitutes for other services. Researchers at Dartmouth Medical School have found that there is significant geographic variation in the use of health care services (Fisher, E., D. Wennberg, T. Stukel, et al. 2003a. The implications of regional variations in Medicare spending. Part 1: The content, quality, and accessibility of care. *Annals of Internal Medicine* 138, no. 4 (February 18): 273–287). These differences are due to the use of discretionary services that are sensitive to the local supply of physicians and hospital beds: physician visits, use of specialists, use of the hospital as a site of care, and diagnostic tests such as imaging. Medicare beneficiaries in regions that provide more services do not have better outcomes or quality. In addition, greater use of imaging is not correlated with lower use of surgical procedures. In a separate study for MedPAC, these researchers found that regions providing more imaging services do not have higher survival rates among Medicare beneficiaries.

Our proposal that the Secretary measure physicians' use of diagnostic tests, hospitalizations, office visits, and other services during an episode of care may help Medicare and providers develop a better understanding of how imaging affects total resource use and quality.

4. Has MedPAC examined volume as it relates to decreases in unnecessary surgery?

We have not studied this question directly. It is difficult to quantify "unnecessary" surgery. Although the volume of some surgical procedures grew relatively slowly between 1999 and 2004 (such as heart bypass surgery and hip fracture repair), other procedures grew more rapidly (such as knee replacement and angioplasty). It is extremely complicated to attribute volume changes in surgical services to growth in imaging. In addition, researchers at Dartmouth have found that greater use of imaging among geographic areas is not correlated with lower use of surgical procedures (see response to question 3).

5. Has volume's relationship to better cancer management and treatment been examined?

MedPAC does not perform research on the appropriateness of specific clinical decisions.

6. Had MedPAC evaluated volume in various types of imaging? How is MedPAC differentiating "good" volume that results in better outcomes? In short, is volume necessarily a bad thing?

We have examined volume growth in many types of imaging services (see Figure 1, attached). We recognize that imaging technology can improve patient outcomes by allowing greater precision in diagnosing and treating patients and, in some cases, substituting for more invasive diagnostic techniques. We also recognize that it is very difficult to distinguish desirable from undesirable increases in imaging volume, which is why we did not recommend a sweeping, across-the-board reduction in imaging payments. Instead, we recommended several targeted changes (see response to question 3). There is evidence that more imaging services do not improve outcomes at the population level, which suggests that not all use of imaging adds value. Researchers at Dartmouth Medical School have found that there is significant geographic variation in per capita volume of imaging services, yet Medicare beneficiaries in regions that provide more imaging services do not have better survival rates.

7. Is MedPAC or CMS aware of any data measuring how defensive medicine factors into imaging growth?

According to the literature, it is very difficult to quantify the costs and extent of defensive medicine. It is difficult to disentangle the many different reasons physicians may order a test, such as a desire to avoid lawsuits or a desire to make a definitive diagnosis. Although some studies have shown that areas with greater risk of malpractice liability have higher use of certain services, it is unclear whether the higher use is related to physicians' concerns about malpractice risk or other factors (such as differences in patients' health status). The Congressional Budget Office (CBO) has examined whether states that adopted malpractice tort limits had lower rates of spending growth for a broad set of conditions, and found no evidence that tort reforms reduced spending (CBO, Cost estimate for H.R. 5, March 10, 2003).

8. Even assuming there is misuse of imaging services what statistical models have you built to determine the amount of misuse that goes on? How does this misuse compare to proper use statistically?

We recognize that it is very difficult to distinguish appropriate from inappropriate use of imaging services, which is why we did not recommend a sweeping, across-the-board reduction in imaging payments. Instead, we recommended several targeted changes (see response to question 3).

9. How does MedPAC quantify the value of imaging? That is, how is imaging's cost effectiveness valued? Is better treatment or a decreased need for surgery recognized? What about cost shifting away from the hospital?

There are examples in the literature where a specific imaging test in a specific clinical situation is cost effective, but there does not appear to be a relationship between more

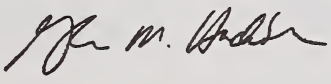
imaging and better outcomes at the population level. Researchers at Dartmouth Medical School have found that there is significant geographic variation in the use of imaging services, yet Medicare beneficiaries in regions that provide more imaging services do not have better survival rates. The researchers also found that greater use of imaging is not correlated with lower use of surgical procedures.

The use of imaging services may not always be consistent with well-accepted clinical guidelines (in cases where guidelines exist). For example, the National Committee for Quality Assurance found that nearly one-fourth of patients with low back pain in managed care plans received unnecessary imaging studies (National Committee for Quality Assurance. 2005. *The state of health care quality: 2005*. Washington, DC: NCQA).

We estimate that about 20 percent of the growth in the volume and intensity of imaging services paid under the physician fee schedule between 1999 and 2002 was related to the migration of imaging from facility settings (such as hospitals) to physician offices and freestanding centers (MedPAC. 2004. *Report to the Congress: Growth in the volume of physician services*. Washington, DC: MedPAC). It is important to note, however, that 80 percent of the growth in fee schedule imaging services was related to factors other than shifts in setting (e.g., advances in technology and practice pattern changes).

If we can be of further assistance, please do not hesitate to contact MedPAC's Executive Director Mark Miller at (202) 220-3700.

Sincerely,

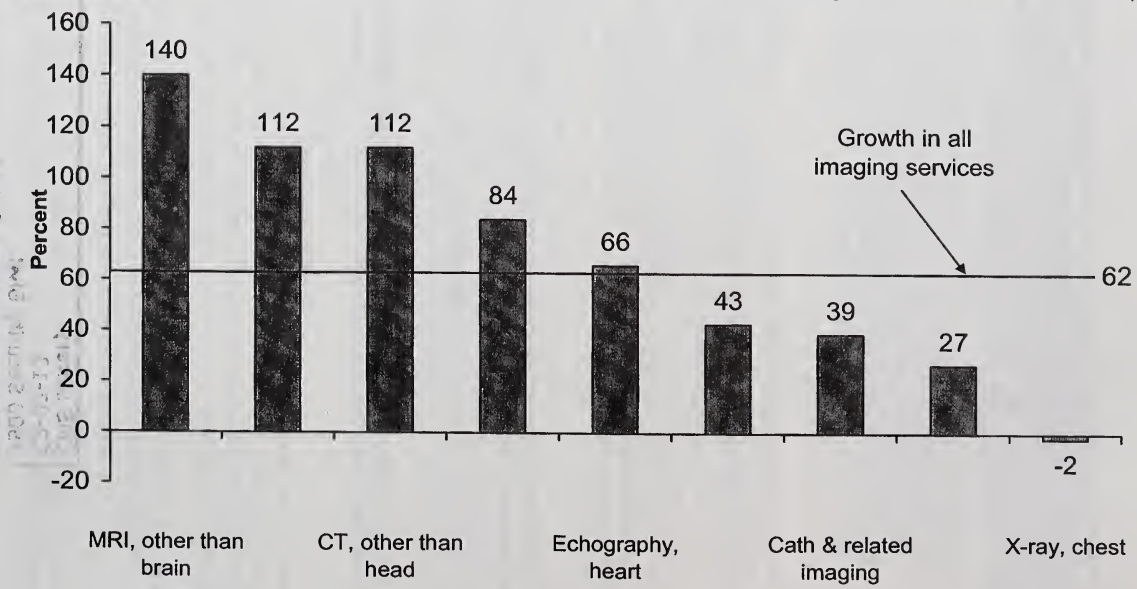


Glenn M. Hackbarth, J.D.
Chairman

CC: The Honorable Nathan Deal

FIGURE 1

Cumulative growth in imaging volume per beneficiary varies (1999–2004)



Note: MRI (magnetic resonance imaging), CT (computed tomography), cath (cardiac catheterization).

Source: MedPAC analysis of Medicare claims data.